

Remarks/Arguments

A. Summary of the claims

Claims 6 and 35 were pending at the time the Action was mailed. Claim 6 has been amended. Support for the amendments may be found generally throughout the specification and original claims, at least at paragraphs [0002] and [0019]. Claim 35 has been canceled. Thus, claim 6 is pending.

Reconsideration of the present case in view of the following arguments is respectfully requested.

B. The Obviousness Rejection is Overcome

Claims 6 and 35 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Application No. 2003/0124184 by Mezaache in view of WO 97/48384 and Orifer F Prenatal Vitamin Supplement (September 25, 1996) ("Orifer F"). The Action asserts that it would be obvious to combine features of Orifer F with the teachings of Mezaache regarding embossed tablets that are said to comprise the presently claimed active ingredients and the teachings of WO 97/48384 regarding imprinting markings on dosage forms to arrive at the presently claimed invention. Action, page 2.

Applicant respectfully traverses. However, in an effort to advance prosecution of this case, claim 35 has been canceled. Regarding the rejection of claim 6, insofar as the rejection may continue to apply to amended claim 6, Applicant respectfully traverses. The cited references considered alone or in combination do not provide a pharmaceutical tablet containing a combination of drugs against excessive nausea and vomiting in pregnant women and having a graphical representation thereon to improve dosage regimen compliance.

Applicant further maintains that Mezaache may not be relied upon as prior art and as such, the present obviousness rejection is moot, as discussed in Applicant's Response to Office Action dated November 25, 2008 ("the November 2008 Response"), and incorporated herein by reference. Despite Applicant's showing that Mezaache is not prior art, Applicant provides arguments to establish that any combination of Mezaache, WO 97/48384 and Orifer F does not render the claimed invention obvious.

1. A Prima Facie Case of Obviousness Has Not Been Established

In making a determination as to whether a *prima facie* case of obviousness exists, the examiner should: (A) determine the "scope and content of the prior art;" (B) ascertain the "differences between the prior art and the claims at issue;" (C) determine "the level of ordinary skill in the pertinent art;" and (D) evaluate evidence of secondary considerations. *Graham v. John Deere*, 383 U.S. 1, 17, (1966); *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007); see also MPEP § 2141.

However, an analysis of these factors in this case does not establish *prima facie* obviousness. For example, a combination of the references fails to teach all the elements of the current claim. Further, in attempting to provide an apparent reason why the cited art, in combination, renders the claimed invention obvious, the Action relies on impermissible hindsight bias. Moreover, there is no reasonable expectation of success regarding any alleged combination of the cited art.

a. The present claims and the cited art

The present invention is directed to solving a problem of poor compliance with physician prescribed dosage regimen. The rejected claim is drawn to subject matter regarding a pharmaceutical tablet that comprises therapeutically effective amounts of two different active

ingredients: doxylamine succinate and pyridoxine hydrochloride. The claim also recites that the tablet comprises a graphical representation of a pregnant woman applied to the tablet surface, where the graphical representation is visible to the naked eye. The claim further recites that the tablet is destined for administration to pregnant women for use against excessive nausea and vomiting and improves patient dosage regimen compliance.

The scope and content of Mezaache is explained in the November 2008 Response, which is incorporated herein by reference. The scope and content of WO 97/48384, and Orifer F are explained in Applicant's Response to Office Action dated March 5, 2008 ("the March 2008 Response"), which is incorporated herein by reference. In summary, Mezaache relates to a quick dissolve composition, where doxylamine succinate and vitamin B6 are mentioned as two possible substances in a composition. Orifer F relates to a prenatal vitamin supplement. WO 97/48384 discloses the general principle of marking the surface of pharmaceutical oral dosage forms.

b. Differences between the rejected claims and the cited art

Differences between the subject matter of the rejected claims and Orifer F and WO 97/48384 are described in the March 2008 Response, which are incorporated herein by reference. Differences between the subject matter of the rejected claims and Mezaache are described in the November 2008 Response, which are incorporated herein by reference. Additional differences are discussed below.

Mezaache further differs from the subject matter of the current claim in the fact, for example, Mezaache relates to a composition where doxylamine succinate and vitamin B6 are mentioned separately at opposite ends of a laundry list including a myriad of possible active ingredients. No example is provided of a composition containing both of the two ingredients.

Similarly, no example is provided that discloses a composition addressing the illness of excessive nausea and vomiting during pregnancy.

Similarly, Orifer F further differs from the subject matter of the current claim in the fact that Orifer F does not relate to a therapeutic drug against pregnancy related illnesses such as excessive nausea and vomiting. Orifer F shows no indication of poor patient dosage regimen compliance and no indication that the packaging graphics have any particular purpose. Further, the graphical representation on the packaging is not intended to and does not necessarily improve poor patient dosage regimen compliance.

Finally, WO 97/48384 further differs from the subject matter of the current claim in that, for example, the reference fails to mention applying any sort of patient dosage regimen compliance improvement in the context of a pharmaceutical treatment of excessive nausea and vomiting during pregnancy.

In view of these differences and those previously identified, there is no disclosure or suggestion in the cited references, individually or in combination, of a pregnancy-friendly indicia directly on a prescription drug pharmaceutical tablet comprising doxylamine succinate and pyridoxine hydrochloride and as such the cited references fail to disclose each element of the current claim. The failure of an asserted combination to teach or suggest each and every feature of a claim remains fatal to an obviousness rejection under 35 U.S.C. § 103.

c. The differences between the rejected claims and the cited art are not obvious differences

The Supreme Court in *KSR* stated that regarding an analysis supporting a rejection under 35 U.S.C. §103(a), it is “important [for an examiner] to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007). Indeed, the Court

indicated that there should be an “explicit” analysis regarding “whether there was an *apparent reason* to combine the known elements *in the fashion claimed* by the patent at issue.” *Id.* (emphasis added).

The Examiner has not provided a reasonable articulated line of reasoning as to why a person of skill in the art would, at the filing date of the present application, have 1) considered Mezaache since it addressed a problem completely unrelated to that of the present invention, and 2) considered it in combination with both WO 97/48384 and Orifer F which also fail to address any problem related to that of the present invention. Rather, the Action simply continues to assert that “it would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize a graphic design on a drug tablet to indicate prenatal (sic) consumption, to use one of Mezaache modified with a figure of Orifer, in order to enhance acceptability & consumption by pregnant women.” Action at page 2.

It appears that the Examiner is relying on hindsight to find a motivation to combine these references. The use of hindsight, however, is not appropriate to establish a motivation to combine. *See W.L. Gore Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983); MPEP § 2143.01 (“The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.”) (emphasis added). The problem of poor patient compliance with dosage regimen has traditionally been addressed by more patient counseling and warnings that discontinuation of prescribed dosage regimen could have tragic results for mother and child to be. Prior to the present invention, no one had ever associated a pregnancy friendly indicia on a tablet as possibly leading to improved patient compliance. The industry knew about poor patient compliance being associated with drug side-effects, bad tasting tablets, complicated dosage regimen or overly large

oral dosage forms. However, any form of association between improved patient compliance and a graphical indicia of a pregnant women being imprinted directly on the dosage form was heretofore unknown. Thus, there was no reasonable expectation of success of such a pregnancy-friendly marking to improve patient dosage regimen compliance, as other strategies for improving patient compliance were available and common. It was surprising and completely against expectation that particular markings on the dosage form itself could lead to a marked advance in patient compliance.

The previously filed 1.132 Declaration of Dr. Gideon Koren indicates that the results achieved by the currently claimed invention were entirely unexpected, as discussed in Applicant's Response to the Office Action dated October 16, 2006 ("the October 2006 Response"), which is incorporated herein by reference, as well as in the March 2008 Response. A copy of the Declaration is attached at Appendix 1. Indeed, in the Declaration of Dr. Koren, submitted with the October 2006 Response, Dr. Koren stated, "*The results reported in the '803 application are unexpected.* One having practical knowledge of paediatrics and obstetrics would have expected little or no clinical effect stemming from graphical representations placed on dosage forms." Koren Declaration, para. 11.2 (emphasis added).

Prior to the present invention, no one had thought to place a pregnancy-friendly indicia directly on a prescription drug pharmaceutical tablet in order to improve poor patient compliance with dosage regimen. The data provided in the patent application clearly shows statistically significant and reproducible improvement in patient perception and concomitant improvement in compliance with dosage regimen. This valuable invention is simply nowhere to be found in the cited references.

d. Secondary considerations

Even if the Office had established a *prima facie* case, which Applicant disputes, sufficient evidence exists to rebut that *prima facie* case. When an applicant submits evidence to rebut the Office's *prima facie* case, the Office must reconsider the initial obvious determination in view of such evidence and the entire record. *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). In this case, the Office has not addressed the numerous objective evidence of nonobviousness previously submitted by the Applicant.

In particular, the Examiner is reminded of the objective evidence of commercial success in this case, which is solely supported by improved patient compliance with dosage regimen. This is discussed in the October 2006 Response. Additionally, the previously filed Declaration by Eric Gervais, filed with the October 2006 Response, is further evidence of commercial success and non-obviousness of the presently claimed invention. A copy of the Declaration is attached at Appendix 2. In brief, the increased sales of the commercialized Diclectin™ tablets having the application of the pregnant woman indicia observed was directly attributed to the claimed application of the pregnant woman indicia on the pharmaceutical tablets, since nothing else was modified in the medicament itself, or in the sales and marketing of the drug. Gervais Declaration at ¶¶ 11-12. This unexpected commercial success, commensurate with and derived from the claimed indicia, constitutes further evidence of the non-obviousness of the present claims. MPEP 716.03.

For the reasons set forth above and set forth in responses to previous Office Actions, including Declaration evidence, claim 6 is not obvious. Reconsideration and withdrawal of the obviousness rejection is respectfully requested.

C. Conclusion

The Examiner is invited to contact the undersigned Attorney at (512) 536-3030 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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Date: April 16, 2009

APPENDIX 1
(Koren Declaration)

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date set forth below as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22343-1450.
Date of Signature
and Deposit: 10/12/06 

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Duchenney Inc.
Serial No.: 10/611,803
Filed: July 1, 2003
Title: PHARMACEUTICAL DOSAGE FORM BEARING PREGNANCY-FRIENDLY INDICIA
Examiner: Hawee, Pili Asabi

DECLARATION UNDER 37 CFR 1.132

Dear Sir:

I, Gideon Koren, of the City of Toronto, Canada, being duly sworn, MAKE OATH AND SAY AS FOLLOWS:

1. This Declaration sets forth my opinion relating to this matter and the basis for my opinion.
1. EXPERIENCE AND QUALIFICATIONS
I am a paediatrician. I was educated and trained at the Sackler School of Medicine, Tel Aviv, Israel and a resident at the Tel Hashomer Hospital, Tel Aviv University, Israel. Since 1988, I am Fellow of the Royal College of Physicians and Surgeons of Canada.
3. I am Acting Ward Chief, The Department of Paediatrics, The Hospital for Sick Children, Toronto. I have held this position since 1986. Between 1992 and 2000 I was the Director, Division of Clinical Pharmacology/Toxicology at the same hospital. Between 1987 and 2000, I was Head, Population Health Sciences at the same hospital. I have also held and/or continue to hold various research roles within The Hospital for Sick Children.

4. I have a particular clinical interest in *Perinatal Toxicology*. Adverse effects of drugs and chemicals in the perinatal period and more specifically on the teratogenic and developmental effects of drugs and chemicals. I planned and currently direct the "Motherisk" program for antenatal counselling of drug/chemical exposure. I have held this position since 1985. "Motherisk" is the first such program in North America and is a prospective project which assesses both exposed mothers and their offspring. Currently we are focusing on the developmental effect of intrauterine exposure to cocaine and carbon monoxide.
5. I also hold teaching roles. I am Professor of Pediatrics, Pharmacology, Pharmacy & Medicine, The University of Toronto. I have held this position since 1993. In 2004, I also became, Professor of Medicine, Paediatrics and Pharmacology/Physiology, University of Western Ontario and The Ivey Chair in Molecular Toxicology, The University of Western Ontario. I have supervised dozens of graduate or post-graduate applicants in their research thesis and fulfillment of degrees.
6. My curriculum vitae is attached as Exhibit A to my Declaration.
7. Thus, I have more than 25 years of clinical experience in the fields of paediatrics and neonatal drug toxicology. I have authored or co-authored over 900 publications in the paediatrics and pharmaceutical field. I have also written or co-written over 20 books and 90 book chapters in these fields. I was invited to give speeches or present research abstracts at different conferences all over the world. My expertise in the pharmaceutical field has been recognized by the honours and awards listed in my curriculum vitae.
8. I am the Editor, Referee or Editor-in-Chief of dozens of peer reviewed scientific journals or books. For example, I am a referee for at least 18 scientific journals including such renowned publications as The New England Journal of Medicine. I am also a long-time member of several professional associations.
- II. UNITED STATES PATENT APPLICATION 10/811,803
9. I have read and considered United States Patent Application 10/811,803.

10. In a nutshell, the Application describes and claims the invention that oral dosage forms having visibly placed thereon, graphical indicia of a pregnant woman, were shown to greatly diminish the expectant mother's perception of risk of drug toxicity for the foetus. As a result of the diminished perception of risk, compliance with a prescribed drug regimen is greatly improved. This is a significant clinical result.

11. In my opinion,

- 11.1. The methodology and results reported in the '803 application are statistically probative;

- 11.2. The results reported in the '803 application are unexpected. One having practical knowledge of paediatrics and obstetrics would have expected little or no clinical effect stemming from graphical representations placed on dosage forms.

I have had a first hand opportunity to witness the clinical results of the invention of the '803 application. Indeed, I have been prescribing the drug sold under the "Diclectin" brand (anti-nauseant for nausea and vomiting during pregnancy).

13. Although a number of publications have proven Diclectin to be innocuous for the foetus, I note in my everyday practice that this drug is still suspected of causing teratogenicity, which clearly affects patient compliance.

14. Yet I have observed that once graphical indicia of a pregnant woman was placed on the pharmaceutical tablets, patient compliance was vastly improved. This, I attribute to the reliable behavioural conditioning effects of the graphical indicia and nothing else.

15. I have seen the "Orifer Prenatal Supplement" showing a graphical indicia of a pregnant woman on its cardboard outer packaging/labelling. However, the "Orifer" product does not present a graphical indicia of a pregnant woman on the dosage forms themselves, i.e. immediately visible prior to ingestion of the dosage form. Furthermore, it is not reported that the "Orifer" product has any effect on the perception of foetal toxicity.

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VI.

CONCLUSION

In my opinion, pharmaceutical tablets of drugs suspected of causing teratogenicity provided with a graphical indicia of a pregnant woman constitute an invention wholly deserving of patent protection and having the clinically observable and statistically reliable effect of diminishing the mother's perception of toxicity to the foetus. This is a highly useful tool for neonatal physicians who struggle with patient compliance because of the perceived risk of foetal toxicity. The invention is not obvious since, to my knowledge, this discovery was never reported in prior publications.

D.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that those statements were made with the knowledge that willful false statements and the like made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Respectfully submitted,

Sent 12/2006
Date


Dr. Gideon Koren

EXHIBIT A
(Dr. Koren's *Curriculum Vitae*)

CURRICULUM VITAE

GIDEON KOREN

DATE OF BIRTH: August 27, 1947

PLACE OF BIRTH: Tel Aviv, Israel

CITIZENSHIP: Canada and Israel

**BUSINESS ADDRESS,
TELEPHONE & FAX**
The Hospital for Sick Children
555 University Avenue
Toronto, Ontario, M5G 1X8
(416) 813-5781
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**HOME ADDRESS &
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84 Lynn Haven Road
Toronto, Ontario, M6B 2K9
(416) 787-6425

EDUCATION:

1961-1965 Tichon Hadash High School, Tel Aviv, Israel

1967-1973 Sackler School of Medicine, Tel Aviv, Israel

POSTGRADUATE TRAINING:

1976-1981 Residency in Pediatrics, Tel Hashomer Hospital, Tel Aviv University, Israel.

1981-1982 Fellowship in Pediatric Nephrology, Tel Hashomer, Tel Aviv University, Hospital, Israel

1982-1984 Fellowship in Pediatric Pharmacology and Toxicology, The Hospital for Sick Children, Toronto (Supervisor: Dr. S.M. MacLeod).

1984-1986 Combined Research Fellowship: Membrane Biology Group, University of Toronto and Pediatric Pharmacology-Toxicology (Supervisors: Drs. M. Silverman & S.M. MacLeod).

POSITIONS HELD:

Director, Motherisk Program, Division of Clinical Pharmacology and Toxicology (1985 -).

Director, Division of Clinical Pharmacology/Toxicology, The Hospital for Sick Children, Toronto (1992-2000).

Staff Pediatrician and Acting Ward Chief, The Department of Pediatrics, The Hospital for Sick Children, Toronto (since July 1986).

Associate Director for Clinical Research, The Research Institute, and The Hospital for Sick Children (July 1988 - January 1998).

Head, Population Health Sciences, The Hospital for Sick Children (October 1997 -2000).

Staff Member of the Division of Clinical Pharmacology-Toxicology, and Division of Hematology/Oncology, The Hospital for Sick Children, Toronto.

Senior Scientist, Research Institute, Hospital for Sick Children.

Pediatric Consultant for The Clinical Institute, The Addiction Research Foundation, Toronto.

Member, University of Toronto, Institute of Bioethics.

Director, The Addiction Research Foundation - HSC Collaborative Program in Toxicology, (1994 - 1997).

Chair, The Steering Committee of the Obstetric Pharmacology Research Units at NIH from (June 2004).

PROFESSIONAL BOARDS:

1981 The Israeli Board of Pediatrics

1985 Diplomat, The American Board of Medical Toxicology

1989 Fellow of the Royal College of Physicians and Surgeons of Canada.

1996 Diplomat, The American College of Medical Toxicology.

MEDICAL LICENSURE:

General License, Israel Ministry of Health, No. 11689.

General License, College of Physicians & Surgeons of Ontario, No. 50992

Nov. 5, 2002 – Human Participant Protections Education for Research – NIH

EDITORIAL BOARDS:

1986 - 1997 The Journal of Toxicology-Clinical Toxicology
1987 - 1996 Developmental Pharmacology and Therapeutics (Associate Editor – 1992 - 1996)
1989 - Pediatric Therapeutics and Toxicology
1990 - Therapeutic Drug Monitoring
1992 - 94 Neonatal Pharmacology Quarterly
1993 - Canadian Journal of Clinical Pharmacology (Associate Editor)
1993 - Neurotoxicology & Teratology
1994 - Annals of Pharmacotherapy
1995 - Biology of The Neonate
1998 - Paediatric Drugs
1998 - Pediatric and Perinatal Drug Therapy.
1999 - Pediatric Research (Consulting Editor).
1999- Current Therapeutic Research
1999 - Journal of Clinical Pharmacology
2000 - J Pediatric Pharmacology & Therapeutics

REGULAR REVIEWER FOR THE FOLLOWING JOURNALS:

Journal of Rheumatology
The New England Journal of Medicine
Journal of Toxicology - Clinical Toxicology (until 1999)
Developmental Pharmacology and Therapeutics (until 1994)
Clinical Pharmacology and Therapeutics
Journal of Pediatrics
Journal of Cardiovascular Pharmacology
Eur J Pediatrics
Teratology
Pediatric Research
Obstetrics & Gynecology
Pediatrics
JAMA
Annals of Pharmacotherapy
Canadian Journal of Clinical Pharmacology
Western J of Medicine
Drug Disposition & Metabolism
New England Journal of Medicine
*Pediatric Drugs
*American Journal of Obstetrics & Gynecology

EDITORIAL ASSIGNMENTS:

- 1) Editor in Chief: Clinical Toxicology book series. Marcel Dekker, NY, 1992-1994.
- 2) Co-editor: Poisoning Medicine North America, December, 1990-1994.
- 3) Editor: The Motherisk Newsletter, The Motherisk Program, 1993-2000.

- 4) Editor: Motherisk Update. Canadian Family Physician, 1994 -
- 5) Associate Editor: Can J of Clin. Pharmacology, 1994-2003.
- 6) Editor in Chief: Therapeutic Drug Monitoring, 2003 -
- 7) Editor in Chief – J FAS Intl., 2003 -
- 8) Editor: Motherisk Grand Rounds. Canadian Journal of Obstetrics & Gynecology, 2005.
- 9) Publisher: Canadian Journal of Clinical Pharmacology, 2004.

MILITARY SERVICE:

1965-1967 Israeli Defense Forces, Medic in Infantry

1974-1975 Israeli Air Force, Flight Surgeon

MEMBERSHIP IN PROFESSIONAL SOCIETIES:

Israeli Medical Association 1973 -
Israeli Society of Clinical Pediatrics 1976 -
The Canadian Society of Clinical Pharmacology 1985 -
The American Board of Medical Toxicology 1985 -
The Canadian Society of Poison Control Centers 1985 -
Canadian Society of Clinical Investigation 1986 -
American Society of Clinical Pharmacology & Therapeutics - 1987 (Vice Chairman of the
Pediatric Section - 1988; Chairman 1990 - 1993)
American Academy of Toxicology 1988 -
Royal College of Physicians & Surgeons of Canada 1989 -
Organization of Teratogen Information Services (Executive committee until 1992) 1990 -
European Society of Developmental Pharmacology 1990 -
The Society for Pediatric Research 1990 -
Teratology Society 1990 -
New York Academy of Sciences 1991 - 1998
Fetal Alcohol Canadian Expertise (FACE): (Founder and Chair) 2000

ACADEMIC APPOINTMENTS:

- 1977 Clinical Instructor in Pediatrics, Sackler School of Medicine, Tel-Aviv University, Israel.
- 1986 - 1989 Assistant Professor of Pediatrics and Pharmacology, the University of Toronto, Divisions of Clinical Pharmacology and Hematology/Oncology, The Hospital for Sick Children, Toronto.
- 1987 Cross appointment with the Institute of Medical Sciences and School of Graduate Studies, University of Toronto.

- 1989 - 1993 Associate Professor of Pediatrics, Pharmacology and Pharmacy, The University of Toronto.
- 1993 Professor of Pediatrics, Pharmacology, Pharmacy & Medicine, The University of Toronto.
- 1986 - 1996 Career Scientist of the Ontario Ministry of Health.
- 1998 Cross appointment in Medical Genetics & Microbiology.
- 2000 Senior Scientist, The Medical Research Council of Canada.
- 2004 The Ivey Chair in Molecular Toxicology, The University of Western Ontario.
- 2004 Professor of Medicine, Pediatrics and Pharmacology/Physiology, University of Western Ontario.

EXTRAMURAL GRANTS

- 2006 – 2009 RSQ/Council du Medicament du Quebec; Antidepressants in pregnancy and fetal outcome (A. Berrard PI) (\$50,000/yr).
- 2005 – 2008 Genom Canada: Adverse Drug Reactions in Children (B Carlton PI) (Total 8 m/3yr) Toronto: (\$100,000/yr).
- 2004 - The Ivey Chair in Molecular Toxicology
- 2004-2005 Health Canada; MotherNature Network (\$75,000/yr).
- 2003-2008 Tel Aviv University- HSC Motherisk Advanced Research (\$50,000/ yr).
- 2003-2008 CIHR: Renal handling of drugs during development (with Dr. Ito). (\$131,000/yr)
- 2002-2006 CIHR: The role of the placenta in fetal toxicology (with Drs. Ito and Einarson). (\$140,000/yr)
- 2002- The Research Leadership in Better Pharmacotherapy During Pregnancy and Lactation. (\$40,000/yr)
- 2003- 2002-2007 CIHR: New Emerging Team (NET): Oxidative damage and biomarkers of FAS (\$250,000/yr)
- 2001 - 2002 Pfizer: The teratogenicity of aspirin in humans. Meta-analysis: (\$120,000).
- 2002 - 2004 Centers for Disease Control: OTIS prospective study on Accutane in pregnancy. (\$120,000 US)
- 2001 - 2002 Glaxo SKB: The safety of ondansetron in pregnancy.

- 2002 – 2004 PSI: Pregnancy outcome in women with polycystic ovary syndrome exposed to metformin (\$50,000) (with Dr. Valois).
- 2002 – 2003 Canadian Foundation for Women's Health. Pregnancy outcome following exposure to beta-blockers (\$40,000) (with Dr. Ray).
- 2002 – 2003 Critical Care Foundation: Errors in drug dosing in children (\$50,000) (with Drs. Parshuram and Bohn).
- 2001 – 2004 Workplace Safety and Insurance Board's Research Advisory Council: Maternal occupational exposure to organic solvents during pregnancy and infant visual processing with: Drs. J. Rovet and C. Estall: (\$252,000).
- 2001 - 2003 Ontario Women's Health Council: Determinants of women's decision-making of antidepressants during pregnancy (\$138, 900).
- 2001 - 2002 Health Canada: Use of biotechnological products during pregnancy and lactation (\$56,000).
- 1999 - 2001 MRC: Comparison of amitriptyline and placebo for the reduction of pain in children with JRA (Brian Feldman PI) (\$16,000).
- 1999 - 2000 Pfizer: Amlodipine in children (PATH 1 & 2) (\$140,000).
- 1999 - 2001 Health Canada: Mother Net (\$350,000/yr).
- 1999 - 2002 Ontario HIV Treatment Network (OHTN): Evaluating safety and risk of antiretroviral drug exposure during pregnancy for infants born to HIV positive women in Ontario/ Investigators: SM King, G. Koren (\$175,000).
- 1999 - 2000 Medical Research Council of Canada: Paediatric Pharmacology Network. (with M. Rieder, S. MacLeod, J. Bend, B. Bailey).
- 1999 - 2002 Glaxo Wellcome - Biochem Pharma, Evaluating safety and risk of antiretroviral drug exposure during pregnancy for infants born to HIV positive women in Canada. Investigators: SM King, G Koren and CPARG.
- 1998 - 2001 March of Dimes (Michael Kramer, PI): Social Disparities in Preterm Births (\$249,978 (US)/yr).
- 1999 - 2001 Health Canada: Breaking The Cycle - Canadian of Substance Abuse project (\$130,000).
- 1998 - 2000 MRC-PMAC (Astra): Omeprazole in pregnancy (\$80,000/yr).
- 1998 - 2000 American Lung Foundation (Co-applicant): Tobacco smoke exposure and infant respiratory function. PI: Judith Groner, Cleveland (\$25,000 US/yr).

- 1990 - 2002 MRC MT 1797: The role of the placenta in perinatal toxicology: Study in a human placental perfusion system (with Dr. L. Derewlany and Dr. S. Ito) (\$70,000/yr).
- 1998 - 2000 Research Institute: Start Up Fund. Maternal smoking and neonatal HIE. (with Drs. Pelman & James) (\$19,000/yr).
- 1984 - 2004 MRC Grant MA 8544: Determinants of Renal Handling of Drugs During Development (\$80,000/yr).
- 1994 Health Canada: Breaking the Cycle Program (\$340,000/yr).
- 1993 - 1997 MRC-PMAC (Ciba Canada): Pregnancy outcome after exposure to antidepressants (\$185,000).
- 1997 - 1998 HIV/AIDS policy and prevention unit, Health Canada: Establishing a national HIV healthline, registry and assessment of outcome of fetal exposure to antiretroviral agents (\$70,000).
- 1997 - 1998 Glaxo Wellcome - Biochem Pharma: Establishing a national HIV healthline, registry and assessment of outcome of fetal exposure to antiretroviral agents. Investigators: SM King, G. Koren.
- 1995 - 1997 MRC-PMAC (Astra): Emla for circumcision pain (\$110,000).
- 1996 - 1998 Scottish Rye Canada: Piracetam for Down's Syndrome (\$30,000).
- 1996 - 1998 Glaxo Wellcome: AZT-TMP-SMX interaction in HIV. (R. BenDayan PI) (\$50,000/yr).
- 1994 Duchesnay, Laval Quebec: Treatment of morning sickness. (\$30,000/yr).
- 1994 Research Institute, Equipment competition: Actigraph unit (with Dr. J. Rovet) (\$6,813).
- 1995 - 1997 Pfizer Ltd: Measurement of compliance of antihypertensive therapy in children (\$42,000).
- 1992 - 1996 International Life Science Institute: "Caffeine intake, levels and effects in children. (with Drs. Kalow and Gillin) (\$35,450/yr (US)).
- 1992 Equipment competition, Research Institute (with Drs. Pencharz & Durie) for Thermoman Microplate reader (\$15,100).
- 1993 - 1996 MRC-Industry: (Apotex Inc.) Comparison of desferal and L_t in thalassemia (with Dr. N. Olivieri) (\$300,000/yr).
- 1994 - 1997 Janssen Pharmaceuticals: Studies of drugs' safety in pregnancy (\$30,000/yr).

- 1994 - 1995 PSI: The safety of beta blockers in pregnancy (with Dr. L. Magee) (\$13,000).
- 1994 - 1995 PSI: The use of oral acyclovir (with Dr. R. Lau) (\$15,000).
- 1995 - 1997 PSI: Pregnancy outcome in infants of binge drinkers (\$55,000/yr).
- 1997 - 1998 PSI: Organic solvents in pregnancy (with Dr. S. Khattak) (\$14,000).
- 1998 - 2001 Brewers' Association of Canada: Fetal Alcohol Syndrome (\$128,000/yr).
- 1994 - 1996 Astra: Studies of EMLA in circumcision (\$61,000).
- 1994 - 1996 Duchesney Ltd: The pharmacokinetics and dynamics of rectal Diclectin for morning sickness (\$50,000).
- 1994 - 1995 Apotex: Studies of L₁ in acute iron poisoning (\$15,000).
- 1994 - 1995 Hospital for Sick Children Foundation. Trial of sequential use of intravenous and oral acyclovir in the therapy of varicella in immunocompromised (\$20,500).
- 1992 - 1993 Physician Services Incorporated Foundation, Randomized trial of one hour versus four hours amphotericin B infusions on febrile reactions in children (with D. Davis and other) (\$33,000).
- 1990 - 1991 PSI: The use of L₁ in acute iron overdose (with Dr. Bentur) (\$14,300).
- 1990 - 1992 Ciba Geigy, Basel & Canada: Effects of antiepileptics on pregnancy outcome. (\$98,000).
- 1991 - 1992 Sherring & Robins Canada Ltd: Safety of brompheniramine in pregnancy (\$26,000).
- 1990 - 1992 PSI: Detection of intrauterine cocaine exposure (\$55,000/yr).
- 1991 Astra Ltd Canada: The use of EMLA for removal of warts (with Dr. N. Shear) (\$22,000).
- 1991 Astra Ltd Canada: The use of EMLA for vaccination (\$42,000).
- 1990 - 1991 Astra Ltd Canada: Feasibility study on EMLA cream (\$40,000).
- 1989 - 1992 MRC: A new oral iron chelator (with N. Olivieri) (\$80,000/yr).
- 1991 - 1993 Janssen Pharmaceutics: Pharmacokinetics & Dynamics of transdermal fentanyl (\$55,000).
- 1991 - 1993 Burroughs Wellcome Canada: Pharmacokinetics and TDM of acyclovir in children (with S. King) (\$25,000).

- 1993 Astra Canada: Pharmacokinetics of penile absorption of EMLA in newborn piglets, (\$35,000).
- 1991 - 1992 Pediatric Consultants: Cyclosporine to reverse multiple drug resistance (with H. Chan) (\$20,000).
- 1988 - 1993 Health and Welfare Canada; Outcome of Pregnancy Following First Trimester Exposure to Cocaine in Social, Non Addict Users in Toronto (\$27,000/yr).
- 1987 - 1989 Leukemia Research Foundation: Operating Grant: Pharmacologic determinants of survival in ALL (\$31,000/yr).
- 1987 Ontario Ministry of Health: The Motherisk Program for drug/chemical exposure in pregnancy (\$80,000/yr).
- 1989 Hoffman La-Roche: Teratogenicity of retinoids & Vitamin A (\$97,000).
- 1989 Astra Pharmaceuticals: EMLA for pain in 3 month - 3 year old children (\$12,000).
- 1989 Equipment grant, the Research Institute, HPLC System, (\$35,000).
- 1988 - 1989 Ciba Geigy Pharmaceuticals: Stability Studies of Desferoxamine (\$8,000).
- 1987 - 1988 Pediatric Consultants: Pharmacokinetic Determinants of Desferal Toxicity (\$9,000).
- 1988 Squibb Canada: Pharmacokinetics and Pharmacodynamics of Captopril in Children with Scarred Kidneys (\$15,000).
- 1988 Astra Pharmaceuticals: Dermal anesthesia with EMLA for children (\$8,000).
- 1988 Knoll Pharmaceuticals: Propafenone use in children with arrhythmias (\$9,000).
- 1987 - 1988 Heart and Stroke Foundation of Ontario Operating Grant: New and improved assay procedures for the measurement of digoxin (with Drs. Soldin and Lingwood) (\$24,000/yr).
- 1987 - 1988 Ontario Ministry of Health Operating Grant: Counselling of Drug/Chemical Exposure During Pregnancy (\$10,000).
- 1986 Renewal of MRC grant MA - 8544.
- 1984 MRC grant MA - 8544: "Determinants of digoxin distribution and excretion in vitro and *in vivo*".
- 1977 Research Grant, Sam Isaac, Tel-Aviv, Israel.

FELLOWSHIPS, SCHOLARSHIPS AND AWARDS

- 1982 Fellowship of the Canadian Foundation for the Advancement of Clinical Pharmacology.
- 1983 Tisdale Award, The Hospital for Sick Children, Toronto. First Research Prize, "Interaction of Digoxin with Co-Administered Drugs: Two Renal Mechanisms".
- 1983 The Pharmacological Society of Canada, Annual Graduate Student Award: Digoxin-Amiodarone Interaction: *In Vivo* and *In Vitro* Studies in Rats". The most outstanding research paper.
- 1983 The Annual Student Award - The Canadian Society of Clinical Investigation.
- 1983 - 1984 Fellowship of The Hospital for Sick Children Foundation.
- 1984 Tisdale Award, The Hospital for Sick Children, Toronto, First Research Prize "Significance of Endogenous Digoxin Like Substance in Newborn and Mothers".
- 1984 Student Award. The Canadian Society of Clinical Pharmacology Annual Meeting, Montreal.
- 1985 Fellowship of The Medical Research Council of Canada.
- 1986 - 96 Career Scientist Award of the Ontario Ministry of Health.
- 1986 Career Scientist Award of the Pharmaceutical Manufacturer Association of Canada (turned down in favor of the previous award).
- 1986 Piafsky's Young Investigator Award of the Canadian Society of Clinical Pharmacology.
- 1986 Travel Award of the Canadian Society of Clinical Pharmacology.
- 1986 Travel Award of the American Federation of Clinical Research.
- 1989 MRC Queen Elizabeth II Visiting Professorship, Western University, London, Ontario.
- 1990 American Academy of Clinical Toxicology Fellowship.
- 1990 Roche Publication Award (NEJM 323: 17-22, 1990); Canadian Society of Clinical Pharmacology.
- 1993 The Distinguished Service Award - The Canadian Society of Clinical Pharmacology.
- 1994 Roche Publication Award (JAMA 1994; 271: 621-623); Canadian Society of Clinical Pharmacology.

- 1994 The Distinguished Service Award - The Research Institute, The Hospital for Sick Children.
- 1995 The Young Investigator Award - The Canadian Society for Psycho-neuropharmacology.
- 1997 The Rawls Palmer Award & Lectureship: The American Society for Clinical Pharmacology & Therapeutics.
- 1997 The Roche Publication Award (N Engl J Med 1997; 337:1-5). The Can Soc Society for Clin Pharmacology.
- 1999 The Irvine Sunshine Award for Excellence in Clinical Toxicology. The International Association for Therapeutic Drug Monitoring and Clinical Toxicology.
- 1999 The Canadian Society for Clinical Pharmacology Senior Scientist Award.
- 2000 - 2005 Senior Scientist Award. CIHR.
- 2001 - The Canadian Society for Clinical Pharmacology – Roche Publication Award.
- 2001 - The Duchesnay Research Leadership in Better Pharmacotherapy During Pregnancy and Lactation.
- 2003 - Canadian Society for Clinical Pharmacology Distinguished Scientist Award.
- 2003 - The International Association for Therapeutic Drug Monitoring and Clinical Toxicology. The Charles Pippenger Award for Excellence in Therapeutic Drug Monitoring.
- 2004 - The Ivey Chair in Molecular Toxicology, University of Western Ontario..
- 2005 - Canadian Society for Clinical Pharmacology Publication Award (J PET: Placental handling of FACE).
- 2005 - Department of Paediatrics, University of Toronto, Inaugural Research Award for Career Excellence.
- 2005 - Canadian Society for Clinical Pharmacology, Roche Publication Award.

COMMITTEES & OFFICIAL POSITION

- 2005 - Chair, Steering Committee, Breaking the Cycle.
- 2002 - Chair, Review Committee for the National Grant Competition for Pediatric CAM.

- 2000 - Mortality & Morbidity Committee, HSC.
- 2000 - Medication Incidents Committee HSC.
- 1998 - NIH: Review Committee for Pediatric Pharmacology Research Units.
- 1998 - 2000 Steering Committees, The Research Institute, HSC.
- 1998 - 2000 President, Canadian Society for Clinical Pharmacology.
- 1997 - 2000 Research Training Committee, HSC.
- 1997 - 1998 Quality Management Committee, The Hospital for Sick Children, Toronto.
- 1996 - 1998 Secretary Treasurer, Canadian Society for Clinical Pharmacology.
- 1998 - 1999 President, Canadian Society for Clinical Pharmacology.
- 1993 - 2000 Chairman, Pharmacy & Therapeutic Committee, The Hospital for Sick Children, Toronto.
- 1992 - 2000 Pharmaceutical Manufacturer Assoc. of Canada: A Member of Advisory Board.
- 1993 - 2000 Deputy Director: Toronto University Program in Clinical Pharmacology.
- 1993 - 1997 Member, MRC Drug Investigation Committee.
- 1982 - 1992 The Human Subject Experimentation Review Committee, The Hospital for Sick Children Toronto. Associate Chairman, 1987, Chairman 1989-92.
- 1987 The Clinical Pharmacology Residency Committee, University of Toronto, Toronto.
- 1988 - 1990 Secretary Treasurer, The Medical Staff Association, The Hospital for Sick Children, Toronto.
- 1988 - 1990 Patient Care Committee, The Hospital for Sick Children, Toronto.
- 1988 - 1996 Third year undergraduate Pharmacology Committee, Dept. of Pharmacology.
- 1988 - 1996 Research Advisory Committee, Research Institute.
- 1989 Coordinator: The Graduate Course in Clinical Pharmacology, Dept. of Pharmacology University of Toronto.
- 1989 - 1992 Chairman of Program Committee, Canadian Society of Clinical Pharmacology.
- 1990 - 1993 Pharmacology Medical Curriculum Renewal, Department of Pharmacology.

- 1990 - 1995 The United States Pharmacopeial Convention; The Pediatric Panel.
- 1992 - 1994 International Union of Pharmacology: Chairman of The Pediatric Pharmacology Section.
- 1992 - 1999 Chair, The Seed Grant Research Competition.
- 1993 - 1999 Chair, Pharmacy & Therapeutics Committee, HSC.
- 1997 Member, Duncan Gordon Fellowship Committee, HSC Foundation
- 1993 - 1999 Member, Humanitarian Award Committee, HSC Foundation.
- 1995 Member, Steering Committee, Breaking The Cycle.
- 1998 - 1999 Chair, Recruitment & retention subcommittee of Steering Committee, Research Institute.
- 2000 - HSC Morbidity Mortality Committee.
- 2000 - HSC Drug Incidence Review Committee.
- 2003 - HSC Foundation Grant Committee on CAM – Chair.
- 2004 - CIHR Grant Committee on Pharmacology & Toxicology.

AREAS OF RESEARCH INTEREST

- 1) *Pediatric pharmacology:* The disposition and effects of drugs on the developing organism. Special interest in the very low birth weight infant and in pediatric cancer chemotherapy. Involves both basic and clinical studies. This work aims at tailoring a rational drug schedule for the developing infant and child.
- 2) *Renal handling of drugs:* Application of various in vitro and in vivo methods to study the handling of drugs by the kidney on a molecular and physiological level. Included are: Clearance studies; binding studies to the brush border and antiluminal membranes; the multiple indicator injection technique; tissue culture studies. Currently I am studying the renal handling of digoxin by the tubular cell. This work is being done in collaboration with Dr. M. Silverman from the membrane group, University of Toronto and supported by the MRC.
- 3) *Perinatal Toxicology:* Adverse effects of drugs and chemicals in the perinatal period. Special interest on the teratogenic and developmental effects of drugs and chemicals. I planned and currently direct the "Motherisk" program for antenatal counselling of drug/chemical exposure. This is the first such program in North America and is a prospective project which assesses both exposed mothers and their offspring. Currently we are focusing on the developmental effect of intrauterine exposure to cocaine and carbon monoxide.

ARTICLES

- 1) Shenfeld Y, Koren G, Shapiro, Y: Cold damage, Part 1. *J Isr Med Assoc* 90:124-126, 1976.
- 2) Shapiro Y, Koren G, Shenfeld Y, Zohar E: Accidental hypothermia. *J Isr Med Assoc* 90:164-166, 1976.
- 3) Koren G, Shenfeld Y, Shapiro Y: Cold damage accidental hypothermia, Part 2. *J Isr Med Assoc* 90:179-183, 1976.
- 4) Shenfeld Y, Shapiro Y, Koren G: Cold damage, Part 3. *J Isr Med Assoc* 90:229-233, 1976.
- 5) Shachar E, Koren G, Frand M: Overdose of chloral derivatives in children. *J Isr Med Assoc* 98:21-22, 1980.
- 6) Koren G, Barzilay Z, Frand M, Brand N: Therapeutic failure with phenytoin in children. *Harefuah* 99:213-214, 1981.
- 7) Koren G, Brand N, Dani S, Halkin H: Poor bioavailability of phenytoin of local production. *Harefuah* 100:355-356, 1981.
- 8) Frand M, Koren G, Rubinstein Z: Reversible hypertrophic osteoarthropathy associated with cyanotic congenital heart disease. *Amer J Dis Children* 136:687, 1982.
- 9) Koren G, Brand N, Dani S, Halkin H: Therapeutic failure in epileptic children due to impaired diphenylhydantoin bioavailability. *Isr J Med Sci* 18:721-723, 1982.
- 10) Koren G, Soldin S, MacLeod S M: Interaction of digoxin with verapamil, indomethacin and other co-administered drugs. A comparative study in rat tissue. In: Proceedings of the International Congress on Developmental Pharmacology, Oct. 1982 (Eds: SM MacLeod, AB Okey, SP Spielberg), Toronto. *Alan R. Liss, Inc., New York*, pp 417-420, 1983.
- 11) Koren G, Soldin S, MacLeod S M: Digoxin-verapamil interaction. *In vitro* studies in rat tissue. *J Cardiovas Pharmacol* 5:443-446, 1983.
- 12) Koren G, Frand M, Barzilay Z, MacLeod SM: Corticosteroid treatment of laryngotracheitis vs spasmodic croup. *Am J Dis Child* 137:941-944, 1983.
- 13) Koren G, Rajchgot P, Good F, Harding L, MacLeod SM: Improved techniques for IV drug delivery in children. *Am J IV Ther Nutr* 10:33-38, 1983.
- 14) Koren G, Modan M, Barzilay Z: Errors in computing drug doses. *Can Med Assoc J* 129:721-723, 1983.

- 15) Koren G, Barzilay Z, Shachar E, Brand N, Dani S, Halkin H: CSF phenytoin in children. *Can J Neurol Sci* 10:195-197, 1983.
- 16) Koren G, Soldin S, MacLeod SM: Digoxin-Amiodarone interaction - in vivo and in vitro studies in rat tissues. *Can J Physiol Pharmacol* 61:1483-1486, 1983.
- 17) Koren G, Frand M, Barzilay Z, MacLeod SM: Corticothérapie comparée de la laryngotrachite et de la laryngite striduleuse chez l'enfant. *J de Pédiatrie* 3:21 - 24, 1983.
- 18) Aladjem M, Aladjem J, Koren G, Boichis H: Maturation of renal tubular transport of gentamicin. *Develop Pharmacol Ther* 7: 82-86, 1984.
- 19) Koren G, Aladjem M, Militiano B, Seegal B, Jhonash A, Boichis H: Ischemic colitis in chronic intermittent peritoneal dialysis. *Nephron* 36:272-274, 1984.
- 20) Koren G, Halkin H, Dani S, Shachar E, Brand N, Barzilay Z: Kinetics of intravenous phenytoin in children. *Pediatr Pharmacol*, 4:31-38, 1984.
- 21) Koren G, Hesslein P, MacLeod SM: Digitalis toxicity associated with amiodarone therapy in children. *J Pediatr* 104:467-470, 1984.
- 22) Koren G, Zarfin Y, Perlman M, MacLeod SM: The influence of indomethacin on digoxin pharmacokinetics in preterm infants. *Pediatr Pharmacol* 4:25-30, 1984.
- 23) Koren G, Brand N, MacLeod SM: Influence of bioavailability on the calculated Michaelis-Menten parameters of phenytoin in children. *Ther Drug Monit* 6:11-14, 1984.
- 24) Koren G, Goresky G, Crean P, Klein J, MacLeod SM: Pediatric fentanyl dosing based on pharmacokinetics during cardiac surgery. *Anesthesia Analgesia*, 63:577-582, 1984.
- 25) Koren G, Boichis C, Rotem Y, Hertz M: The chest x-ray in the diagnosis of atypical nephritis due to infectious mononucleosis. *J Can Assoc Radiol* 35:308-309, 1984.
- 26) Koren G, Crean P, Klein J, Goresky G, Villamater J, MacLeod SM: Sequestration of fentanyl by the cardiopulmonary bypass. *Eur J Clin Pharmacol* 27:51-56, 1984.
- 27) Koren G, MacLeod SM: Difficulty in achieving therapeutic serum concentration of salicylate in Kawasaki disease. *J Pediatr*, 105: 991-995, 1984.
- 28) Koren G, MacLeod SM: Characteristics of the digoxin-quindidine and a digoxin-verapamil interaction in rat kidney. *Res Comm Chem Pathol Pharmacol* 45: 3-18, 1984.
- 29) Koren G, Farine D, Maresky D, Taylor J, Heyes J, Soldin S, MacLeod SM: Significance of the endogenous digoxin-like substance in infants and mothers. *Clin Pharmacol Ther* 36: 759-764, 1984.

- 30) Koren G, Goresky G, Crean P, Klein J, MacLeod SM: The pharmacokinetics of fentanyl in children with renal disease. *Res Comm Chem Path Pharmacol* 46: 371-379, 1984.
- 31) Koren G, MacLeod SM: Postmortem redistribution of digoxin in rats. *J Forens Sci* 30: 92-96, 1985.
- 32) Koren G: Interaction between digoxin and commonly coadministered drugs in children. *Pediatrics* 75:1032-1037, 1985.
- 33) Zarfin Y, Koren G, Maresky D, Perlman M, MacLeod SM: Possible indomethacin aminoglycoside interaction in preterm infants. *J Pediatr* 106:511-513, 1985.
- 34) Butt W, Robert Gow, Whyte H, Smallhorn J, Koren G: Complications of arterial catheters: Retrograde Flow and Rapid Elevation in Blood Pressure. *Pediatrics* 76:250-254, 1985.
- 35) Butt W, Koren G, England S, Shear N, Whyte H, Bryan CA, Swyer PR: Hypoxemia associated with helium-oxygen therapy in children. *J Pediatr* 106:474-477, 1985.
- 36) Koren G, Rajcgot P, Harding E, Perlman M, MacLeod SM: Evaluating a filter device used for intermittent intravenous drug delivery to newborn infants. *Amer J Hosp Pharm* 42:106-108, 1985.
- 37) Koren G, Greenwald M: Decreased theophylline clearance causing toxicity in children during viral epidemics. *J Asthma* 22:75-80, 1985.
- 38) Koren G, Greenwald M: Summer Camp Medicine; The epidemiology of beta streptococcal infections. *Can J Pub Health* 73:63-64, 1985.
- 39) Koren G, Shear N, Macleod SM: In vitro assessment of the digoxin-quinidine interaction using cultured human cells. *JRCs of Med Sci* 13:72-73, 1985.
- 40) Koren G, Lavi S, Greenwald M, Roifman CH, MacLeod SM, Gelfand E: Cerebrospinal fluid pharmacokinetics of tobramycin, ceftazidime, phenobarbitone and phenytoin in a child. *Clin Pharmacokinet* 10:371-375, 1985.
- 41) Koren G, Weitzman Z, Forstner G, Durie P: BT PABA test in evaluating exocrine pancreatic function in CF patients: A pharmacokinetic approach. *J Digest Dis Sci* 30:928-932, 1985.
- 42) Koren G, Barker C, Bohn D, Kent G, Biggar D: Influence of hypothermia on gentamicin and theophylline in piglets. *Crit Care Med* 13:844-847, 1985.
- 43) Koren G, Leeder S, Harding L, MacLeod SM: Optimization of gentamicin therapy in VLBWI. *Pediatr Pharmacol* 5:79-88, 1985.
- 44) Koren G, Sloan I: Pharmacokinetics of N₂O in children. *Res Comm Chem Pathol Pharmacol* 49:95-108, 1985

- 45) Koren G, Parker R: Interpretation of excessive serum concentration of digoxin in children. *Amer J Cardiol* 55:1210-1214, 1985.
- 46) Koren G, Chin T, Correia J, Tesoro A, MacLeod SM: Theophylline pharmacokinetics in adolescent females following coadministration of oral contraceptives. *Clin Invest Med* 8: 222-226, 1985.
- 47) Koren G, Soldin S, MacLeod SM: Organization and efficacy of a therapeutic drug monitoring consultation service in a pediatric hospital. *Ther Drug Monit* 7: 295-298, 1985.
- 48) Collins C, Koren G, Crean P, Klein J, Roy WL, MacLeod SM: The correlation between fentanyl pharmacokinetics and pharmacodynamics in preterm infants during ligation of PDA. *Anesth Analg* 64:1078-1080, 1985.
- 49) Koren G, Butt W, Chinyanga H, Pape K: Neonatal seizures associated with morphine sulphate. *Vet Hum Toxicol* 27:519-520, 1985.
- 50) Koren G, James A, Perlman M: A simple method for the estimation of GFR in newborn infants using routine gentamicin serum concentrations. *Clin Pharmacol Ther* 38:680-685, 1985.
- 51) Koren G, Lavi S, Rose U, Rowe R: Probable efficacy of high dose salicylate in reducing coronary involvement in Kawasaki disease. *JAMA* 254: 767-769, 1985.
- 52) Koren G, Butt W, Chinyanga H, Soldin S, Tan YK, Pape K: Postoperative morphine infusion in newborn infants: Assessment of disposition characteristics and safety. *J Pediatr* 107: 963-966, 1985.
- 53) Sirota L, Aladjem M, Laufer J, Boichis H, Koren G: Gentamicin-digoxin interaction in the rat kidney. *Isr J Med Sci* 21:535-536, 1985.
- 54) Koren G, Butt W: The efficacy of racemic epinephrine in subglottic stenosis in neonates: a controlled prospective study. *J Perinatol* 6:24-26, 1986.
- 55) Koren G, Butt W, Meyer J, Pape K, MacLeod SM: Paraldehyde pharmacokinetics and seizure control in newborn infants. *Neurology* 36:108-111, 1986.
- 56) Koren G, Zarfin Y, Maresky D, Spiro T, MacLeod SM: Pharmacokinetics of intravenous clindamycin in newborn and infants. *Pediatr Pharmacol* 5:287-292, 1986.
- 57) Crean P, Koren G, Goresky G, Klein J, MacLeod SM: Fentanyl-oxygen vs Fentanyl N2O/oxygen anesthesia in children undergoing cardiac surgery. *Can J Anesth* 33:32-36, 1986.
- 58) Koren G, Lavi S, Rose V, Rowe R: Kawasaki disease; a review of risk factors for coronary aneurysms. *J Pediatr* 108:388-392, 1986.

- 59) Koren G, Goresky G, Crean P, Klein J, MacLeod SM: Unexpected alterations in fentanyl pharmacokinetics in children undergoing cardiac surgery: Age related or disease related? *Devel Pharmacol Ther* 9:183-191, 1986.
- 60) Koren G, Barzilay Z, Greenwald M: Ten-fold errors in drug dose administration: A neglected hiatrogenic disease in children. *Pediatrics* 77:848-849, 1986.
- 61) Koren G, Spielberg SP, MacLeod SM: Opinions of Canadian Pediatricians on controversial therapeutic issues. *J Med Ed* 61:769-771, 1986.
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- 75) Koren G, James A: Vancomycin dosing for preterm infants. Prospective verification of new recommendations. *J Pediatr* 110:797-798, 1987.
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- 102) Doyle JJ, Koren G, Cheng MY, Blanchette VS: Anticoagulation with sodium warfarin in children: Effects of loading regimen *J Pediatr*, 113: 1095-1097, 1988.
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- 104) Bailey B, Morris P, McMartin KI, Klein J, Duhart HM, Gillam MP, Binienda Z, Slikker W, Paule MG, Koren G: Transplacental pharmacokinetics of cocaine and benoylcgonine in plasma and hair of Rhesus monkeys. *Reprod Toxicol* 12: 517-523, 1988.
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PRESENTATIONS

- 1) June 1979, Tel-Aviv: The annual meeting of the Israeli Society of Clinical Pediatrics: Dexamethasone in laryngotracheitis.
- 2) June 1981, Tel-Aviv: The annual meeting of the Israeli Society of Clinical Pediatrics: Errors in computing drug dosage - an interdivisional study.
- 3) June 1981, Tel-Aviv: The annual meeting of the Israeli Society of Clinical Pediatrics: Determination of optimal phenytoin dosage in children by graphic analysis of Michaelis Menten Kinetics.
- 4) June 1982, Tel-Aviv: The annual meeting of the Israeli Society of Clinical Pediatrics: Intravenous phenytoin in children.
- 5) June 1982, Tel-Aviv: The annual meeting of the Israeli Society of Clinical Pediatrics: Maturation of renal transport of gentamicin in the rat. *Isr J Med Sci.*
- 6) October 1982, Toronto: International Symposium on Developmental Pharmacology: Interaction of digoxin with verapamil, indomethacin and other coadministered drugs. A comparative study in rat tissue.
- 7) February 1983, Toronto: Pediatric Update: Controversies in the treatment of croup.
- 8) March 1983, San Diego: The annual meeting of the American Society for Clinical Pharmacology and Therapeutics: Intravenous phenytoin in children.
- 9) March 1983, San Diego: The annual meeting of the American Society for Clinical Pharmacology and Therapeutics: CSF phenytoin in children.
- 10) March 1983, San Diego: The annual meeting of the American Society for Clinical Pharmacology and Therapeutics: Dixogin-verapamil interactions: *in vitro* studies in rat tissues.
- 11) April 1983, San Diego: The annual meeting of the American Academy of Neurology: The influence of impaired bioavailability on the Michaelis Menten kinetics of phenytoin in children.
- 12) May 1983, Washington, DC: The annual meeting of the American Society for Pediatric Research: Steroids in the treatment of laryngotracheitis vs. spasmodic croup in children.
- 13) May 1983, Washington, DC: The annual meeting of the American Society for Pediatric Research: The influence of indomethacin on digoxin pharmacokinetics in preterm infants.
- 14) June 1983, Ottawa: The annual meeting of the Canadian Federation of Biological Societies: Digoxin Amiodarone interaction. *In vivo* and *in vitro* studies in rat.

- 15) August 1983, Washington, DC: The second international meeting on Clinical Pharmacology and Therapeutics: Digoxin indomethacin interaction in preterm infants.
- 16) September 1983, Calgary: The annual meeting of the Canadian Society of Clinical Investigation: The interaction of digoxin with coadministered drugs.
- 17) October 1983, Toronto: Workshop: "Digoxin: Research Issues for the Eighties". a) Interactions of digoxin with coadministered drugs. b) Postmortem redistribution of digoxin.
- 18) March 1984, Reno, Nevada: Irreversible binding of fentanyl by the cardiopulmonary bypass. The annual meeting of the International Meeting of Anesthesiology Research.
- 19) March 1984, Atlanta, Georgia: Kinetics of amiodarone associated digoxin toxicity in children. Plenary Session, American Society of Clinical Pharmacology Annual Meeting.
- 20) May 1984, San Francisco: Unexpected abnormalities of fentanyl disposition in children undergoing cardiac surgery. American Society of Pediatric Research, Annual Meeting.
- 21) May 1984, San Francisco: Characteristics of digoxin interaction with quinidine, verapamil and amiodarone: *in vivo* and *in vitro* studies. American Society of Pediatric Research, Annual Meeting.
- 22) June 1984, Toronto: Improved gentamicin dosing based on pharmacokinetics in preterm infants. Plenary Session. The Canadian Pediatric Society.
- 23) September 1984, Montreal: The Canadian Society of Clinical Investigation Annual Meeting: Significance of Endogenous Digoxin-like Substance in Neonates and Mothers.
- 24) September 1984, Montreal: The Canadian Society of Clinical Investigation: Improved Intravenous Delivery of Antibiotics in the Newborn.
- 25) September 1984, Montreal: The Royal College of Physicians and Surgeons of Canada, Annual Meeting: Optimization of TDM System.
- 26) October 1984, New Orleans: The Annual Meeting of The American Society of Anesthesiologists. Fentanyl Anesthesia for Cardiac Surgery in Children: a) Fentanyl Oxygen vs. Fentanyl N₂O, b) Relationships between Drug Concentrations and Pharmacodynamics.
- 27) March 1985, San Antonio: The 86th Meeting of the American Society of Clinical Pharmacology & Therapeutics: The pharmacokinetics of clindamycin in newborn infants.
- 28) March 1985, San Antonio: The 86th Meeting of the American society of Clinical Pharmacology & Therapeutics: Endogenous digoxin-like substance in infants & mothers: pharmacokinetic and pharmacodynamic implications.

- 29) May 1985, Washington DC: The Society of Pediatric Research Annual Meeting: Endogenous digoxin like substance in infants and mothers.
- 30) May 1985, Washington DC: The Society of Pediatric Research Annual Meeting: Probable efficacy of salicylates in reducing coronary involvement in Kawasaki disease.
- 31) May 1985, Chicago: The Society of Critical Care Medicine Annual Meeting: The influence of hypothermia on the pharmacokinetics of gentamicin and theophylline in piglets.
- 32) August 1985, Kansas City: The American Academy of Clinical Toxicology annual meeting. Morphine-induced seizures in newborn infants.
- 33) August 1985, Kansas City: The American Academy of Clinical Toxicology. Ten-fold errors in calculation of drug doses in children; a neglected hiatrogenic disease.
- 34) September 1985, Vancouver: The Canadian Society of Clinical Investigation annual meeting: Digoxin uptake by the dog kidney.
- 35) September 1985, Vancouver: The Canadian Society of Clinical Investigation annual meeting: Paraldehyde pharmacokinetics and seizure control in newborn infants.
- 36) March 1986, Washington DC: The American Society of Clinical Pharmacology and Therapeutics annual meeting: Interaction of digoxin with quinidine and verapamil in the brush border of the dog kidney.
- 37) March 1986, Washington DC: The American Society of Clinical Pharmacology and Therapeutics annual meeting: Alfentanil - a pharmacokinetically predictable drug in children.
- 38) April 1986, St. Louis Missouri: FASEB annual meeting: Application of novel in vivo and *in vitro* methods to study renal digoxin handling.
- 39) May 1986, Washington DC: Annual meeting of SPR: Application of novel in vivo and *in vitro* methods to the study of renal digoxin hand ling.
- 40) May 1986, Washington DC: Annual meeting of SPR: Pharmacokinetic determinants of 6MP myelotoxicity and therapeutic failures in children with ALL.
- 41) May 1986, Washington DC: Annual meeting of SPR: Ten fold errors in computation of drug doses in children - a neglecter triatogenic disease.
- 42) May 1986, Kingston, Ont.: The Annual meeting of the Genetic Counselors of Ontario: Motherisk - a new approach to antenatal counselling of drug and chemical exposure.
- 43) May 1986, St. Catherines, Ont.: In: "Future Directions in Planning and Implementing Programs for the Prevention of Developmental Handicaps. Organized by The Western NY Task Force on Prevention of Mental Retardation and the Ontario Association for the Mentally Retarded. "Chemical and Physical Hazards and the Fetus."

- 44) July 1986, Stockholm Sweden: The III World Conference on Clinical Pharmacology: Application of novel in vivo and in vitro methods to the study of renal digoxin handling.
- 45) July 1986, Stockholm Sweden: The III World Conference on Clinical Pharmacology: Pharmacokinetic determinants of 6MP myelotoxicity and therapeutic failures in children with ALL.
- 46) September 1986, Toronto: The annual meeting of the Canadian Society of Clinical Investigation: Digoxin handling by the renal tubular cell.
- 47) September 1986, Toronto: The annual meeting of the Canadian Society of Clinical Investigation: Vancomycin pharmacokinetics and dose recommendations for preterm infants.
- 48) September 1986, Santa Fe: The annual meeting of the American Academy of Toxicology: Motherisk - a new approach to drug/chemical exposure in pregnancy.
- 49) September 1986, Santa Fe: The annual meeting of the American Academy of Toxicology: Cellular mechanisms of digoxin transport and toxic interactions in the kidney.
- 50) October 1986, New York: The Eastern Section of APCR: Digoxin handling by the renal tubular cell.
- 51) October 1986, Toronto: Research with children: ethics and implementation. International Meeting "The Responsibility of the Investigator".
- 52) November 1986, Toronto: 2nd Annual Perinatal Day. Drug effects on the fetus.
- 53) November 1986, Buffalo NY: Third annual conference for prevention of mental retardation and developmental disabilities. "Teratogenic cause of developmental disabilities".
- 54) January 1987, Children's Hospital of Winnipeg, Manitoba: The Ian Goldberg Lectureship in Pediatrics.
- 55) February 1987, Children's Hospital of Ottawa: "Motherisk - A New Approach to Drug/Chemical Teratogenicity".
- 56) March 1987, Orlando, Florida: Annual Meeting of the American Society of Clinical Pharmacology (Plenary session): Physician compliance as a risk factor in acute lymphoblastic leukemia.
- 57) April 1987, Cincinnati, Ohio: 20th anniversary of the Poison Control Center, "A New Approach to Drug/Chemical Teratogenicity".
- 58) April 1987, Cleveland, Ohio: Rainbow's Babies and Children's Hospital: Glaxo lectureship.

- 59) April 1987, Anaheim, Society of Pediatric Research: Pharmacokinetics and respiratory pharmacodynamics of IV salbutamol in neonates with BPD.
- 60) June 1987, Hamilton, Ontario: Canadian Society of Laboratory Technicians: A New Approach to Chemical Exposure in Pregnancy.
- 61) September 1987, Winnipeg, Manitoba: Annual Meeting of the Canadian Society for Clinical Investigation: Simultaneous inhibitors of renal tubular and biliary transport of digoxin.
- 62) September 1987, Winnipeg, Manitoba: Annual Meeting of the Canadian Society for Clinical Investigation: Motherisk-A new approach to drug/chemical induced teratogenicity.
- 63) October 1987, Smolenice, Czechoslovakia: Perinatal Pharmacology Meeting: Ethics of drug studies in infants.
- 64) March 1988, Toronto, Ontario: Annual Meeting of The Clinical Research Society of Toronto: Pharmacological determinants of survival in childhood leukemia.
- 65) April 1988, Les Diablerets, Switzerland: European Society of Developmental Pharmacology: Pharmacokinetics, dose recommendations and safety of amphotericin B in infants and children.
- 66) April 1988, Boston, MA: Teratogen Information Services Workshop: Perception of teratogenic risk by pregnant women exposed to drugs and chemicals in pregnancy.
- 67) May 1988, Washington DC: Annual Meeting of SPR: The effects of quinidine on the renal tubular and biliary transport of digoxin.
- 68) June 1988, Toronto, Ontario: American College of Physicians - Complications of Pregnancy Workshop: Prescribing in pregnancy.
- 69) September 1988, Baltimore MD: Annual meeting of the American Academy of Clinical Toxicology: The Effect of Hypothermia on the Disposition of Ethanol in Piglets.
- 70) September 1988, Ottawa: The Annual Meeting of the Canadian Society of Clinical Investigation: Pharmacokinetics and Safety of Amphotericin B in children.
- 71) November 1988, Tokyo Japan: 3rd International Conference of Kawasaki Disease: Salicylates in Kawasaki Disease.
- 72) January 1989, London Ontario: MRC Queen Elizabeth II Visiting Professor. Western University, London.
- 73) January 1989, Miller's Children Hospital, Long Beach California: The effects of drugs in pregnancy.

- 74) March 1989, Nashville Tennessee: The annual meeting of the American Society of Clinical Pharmacology & Therapeutics: Perinatal Toxicology (Symposium).
- 75) March 1989, London UK: IUPHAR Pediatric Pharmacology Network meeting.
- 76) April 1989, Charlottesville Virginia: The Bird song Annual conference: Therapeutic drug monitoring in children.
- 77) May 1989, Washington DC: The annual meeting of the Society for Pediatric Research: Diurnal variation of 6mP pharmacokinetics and myelotoxicity in children.
- 78) July 1989, Manneheim, Germany: The World Conference in Clinical Pharmacology: Randomized, cross over comparison of iron excretion between deferoxamine and the new oral chelator L₄.
- 79) July 1989, Paris: The 19th World Conference in Pediatrics; Symposium: 3rd generation cephalosporin use in neonates.
- 80) September 1989, Edmonton, Alberta: The Canadian Society of Clin. Pharmacology annual meeting: Randomized, crossover comparison of iron excretion between deferoxamine and L₄.
- 81) September 1989, Edmonton Alberta: Diurnal variation in 6-MP pharmacokinetics and myelotoxicity in children with leukemia.
- 82) October 1989; Atlanta Georgia: Annual meeting of the American Academy of Toxicology. Fetal outcome following carbon monoxide poisoning in pregnancy.
- 83) October 1989; Long Beach California: Workshop on ribavirin: Safety of ribavirin in pregnancy.
- 84) November 1989; New Brunswick, New Jersey, Department of Pediatrics: New frontiers in pediatric pharmacology.
- 85) February 1990: Salt Lake City: 3rd international conference of teratogen information services: Lithium in pregnancy.
- 86) March 1990: San Francisco Ca.: Annual meeting of the American Society of Clinical Pharmacology, Symposium: EMLA a novel.
- 87) May 1990: Los Angeles: The Society of Pediatric Research: Variability of 6-MP exposure.
- 88) May 1990: Tremezzo, Italy: The European Society of Developmental Pharmacology: Ethics of Research in Pediatrics.
- 89) June 1990: Strbske Pleso, Slovakia: Adverse drug effects in Pediatrics: ADR in pregnancy.

- 90) September 1990: Tucson AZ: American Academy of Clinical Toxicology symposium "Maternal-Fetal Toxicology".
- 91) October 1990: Barcelona Spain: TDM meeting: TDM in pregnancy.
- 92) October 1990: Barcelona, Spain: TDM meeting: Hair testing for gestational cocaine exposure.
- 93) October 1990: Barcelona Spain: TDM meeting: Cardiac glycosides.
- 94) November 1990: FDA, Washington DC: Pharmacokinetic determinants of survival in childhood leukemia.
- 95) November 1990: Ottawa: Symposium "Risk estimation of pharmaceuticals". Risk estimation in pregnancy.
- 96) December 1990: Ashkelon Israel: Israeli Society of Clin. Pediatrics Annual Meeting: Novel approaches in pediatric pharmacology.
- 97) February 1990: Ottawa: Health Protection Branch: Drug therapy in children.
- 98) March 1991: San Antonio Texas: Annual meeting, Amer Soc. Clin. Pharmacol symposium: Measuring cocaine in neonatal hair.
- 99) April 1991: Chicago IL: Annual meeting, Teratology Information Services. Quality Assurance in TIS.
- 100) May 1991: New Orleans: Annual meeting of the Society for Pediatric Research: Pregnancy-induced changes in drug metabolism in epileptics.
- 101) May 1991: New Orleans: Annual meeting of The Society for Pediatric Research. Use of Medication Event Monitor System.
- 102) June 1991: Ramat Gan Israel: International Society of Chronobiology. "Diurnal variation of methotrexate pharmacokinetics".
- 103) September 1991: Quebec City: Royal College annual meeting: The use of EMLA in pediatric pain.
- 104) October 1991: Toronto: Annual meeting of the American Academy of Clinical Toxicology: Risk evaluation of drugs in pregnancy.
- 105) October 1991: Tours, France: 46th meeting of the French Association of Pharmacologists: Ethics of drug studies in pediatrics.
- 106) November 1991: Vancouver BC: Dept. of Genetics, U.B.C. Cocaine in pregnancy.

- 107) November 1991: BC Children's Hospital Vancouver: The use of EMLA in pediatric pain.
- 108) November 1991: Victoria General Hospital, Victoria BC: The use of EMLA in pediatric pain.
- 109) November 1991: Calgary: Children's Hospital of Alberta, Dept. of Anesthesia: The use of EMLA in pediatric pain.
- 110) November 1991: Calgary: Children's Hospital of Alberta, Dept. of Pediatrics: New approaches to pediatric pain.
- 111) November 1991: Edmonton: University of Alberta Hospital, Dept. of Dermatology: EMLA for hiatrogenic pain.
- 112) November 1991: Ottawa General Hospital: Dept. of Anesthesia, EMLA for pediatric pain.
- 113) November 1991: Children's Hospital of Western Ontario, London: Dept. of Pediatrics: EMLA for pediatric pain.
- 114) November 1991: Children's Hospital of Columbus Ohio: The 1991 Wheeler's Professorship: Medication errors in children.
- 115) February 1992: Child Health 2000, Vancouver: Fetal exposure to drugs and chemicals.
- 116) February 1992: Child Health 2000, Vancouver: Environmental risks to the fetus.
- 117) April 1992: The Organization of Teratology Information Services, SanDiego: Reproductive risks of ribavirin.
- 118) May 1992: European Society of Developmental Pharmacology, Borgholm, Sweden: Hair test: Biological markers for gestational exposure to cigarette smoking and cocaine.
- 119) May 1992: New York Academy of Sciences, San Diego: Nutrition in Pregnancy workshop: Perception of teratogenic risk.
- 120) June 1992: The Teratology Society, Boca Raton, Fla: Perception of teratogenic risk.
- 121) June 1992: The Teratology Soceity, Boca Raton Fla: Research in reproductive toxicology.
- 122) August 1992: The International Pediatric Nephrology Association, Jerusalem Israel: Novel approaches to study kidney-drug interactions.
- 123) July 1992: Canadian Therapeutic Update 1992, Niagara on the Lake: The use of EMLA.
- 124) August 1992: International Society for Pediatric Pharmacology, Jerusalem: Novel Ways to Study Kidney-Drug Interations During Development.

- 125) September 1992: International workshop in pediatric pharmacology, Smolenice, Slovakia: (1) Maternal Fetal Toxicology, (2) "Awakening".
- 126) September 1992: The Can. Society of Clin Pharmacology, Ottawa, Ontario: The effect of ECMO on drug disposition in children.
- 127) September 1992: The Can Pediatric Society, Ottawa, Ontario: Drug of abuse in pregnancy.
- 128) October 1992: The Amer College of Rheumatology, Atlanta, Georgia: The role of the placenta in drug transfer.
- 129) November 1992: Montreal's Children Hospital: Biological markers of intrauterine exposure to cocaine and cigarette smoke.
- 130) November 1992: Mead Johnson Perinatology Training Program; Marco Island, Fla: (1) Bias against the null hypothesis. (2) Biological markers of intrauterine exposure to cocaine.
- 131) December 1992: Ottawa, Ontario: National Council on Bioethics in Human Research; Workshop on the Ethics of Research Involving Children. (1) The perspective of research ethics boards. (2) Current procedures for protection of children in research.
- 132) January 1993: Palm Beach Fla: Pro Cóm International: Round Table on New Approaches to Local Anesthesia: The Use of EMLA in Pediatrics.
- 133) March 1993: Honolulu, Hawaii, American Society of Clinical Pharmacology annual meeting: Perinatal exposure to NSIDS (*Presentation in Symposium*).
- 134) March 1993: Chicago, Il: American Academy of Pediatrics: Medication errors in children.
- 135) April 1993: Vancouver, BC: Annual drug therapy medications in pregnancy; pain therapy in children.
- 136) May 1993: Washington, DC: Society for Pediatric Research: Nephrotoxicity of Ifosfamide and cisplatin (Presented in symposium).
- 137) May 1993: Indianapolis, In. Poison control center annual day: Poisoning in pregnancy.
- 138) June 1993: Saskatoon and Regina: Saskatchewan Institute on Prevention of Handicaps: Role of folic acid in preventing neural tube defects.
- 139) December 1993: Halifax, NS: Health Canada Workshop on FAS: Fetal Alcohol Syndrome. The Motherisk Approach.

- 156) February 1995: Toronto, Ont.: Drug Information Association: Safety of Drugs in Pregnancy.
- 157) February 1995: Ottawa, Ont.: Grand Round, Dept. of Obstetric/Gynecology: Safety of Drugs in Pregnancy.
- 158) April 1995: Toronto, Ont.: The First Motherisk International Course: Human Teratogens; Drugs of abuse in pregnancy.
- 159) May 1995: Quebec City: Annual Meeting, Canadian College of Family Physicians: Drugs in pregnancy.
- 160) May 1995: Vancouver: Child Health 2000: Environmental risks in pregnancy.
- 161) June 1995: Vancouver: The Can Soc for Neuro psycho pharmacology: Biological markers for intrauterine drug exposure.
- 162) September 1995: Montreal, Quebec: Annual Meeting: Royal College: Novel methods to measure kidney drug interactions.
- 163) September 1995: Rochester, NY: Annual North American Toxicology Meeting: Treating the mother-protecting the unborn.
- 164) November 1995: Istanbul Turkey: International Herpes Management Forum: Varicella in Pregnancy.
- 165) November 1995: Jerusalem, Hadassa Mt. Corpus: Drugs in prengancy and lactation.
- 166) December 1995: Braselton, Georgia: Safety and Toxicity of Nicotine. Nicotine and cigarette smoke in pregnancy.
- 167) January 1996: Palm Spring, Cal.: Biological markers of fetal exposure to drugs. Annual Sudden Infant Death Syndrome meeting, Shriner Institute.
- 168) February 1996: Toronto: Bias against the null hypothesis in reproductive toxicology. Annual Drug Information Association Meeting of the Toronto Drug Safety Research Group.
- 169) March 1996: San Diego, Cal.: "Treating the Mother-Protecting the Unborn". The annual meeting, American Society of Clinical Pharmacology and Therapeutics.
- 170) May 1996: Quebec City: Drugs in pregnancy - an update. Annual meeting. The Canadian College of Family Physicians.
- 171) May 1996: Pecs Hungary: New frontiers in pediatric pharmacology. 5th Congress of the European Society for Developmental Pharmacology.
- 172) July 1996: Niagara-on-the-Lake: New frontiers in pediatric drug therapy.

- 173) October 1996: Toronto, Ont.: Risks of prenatal exposure to drugs, "Addiction in Pregnancy" Conference. The Infant Mental Health Project.
- 174) November 1996: Toronto, Ont.: Update on drugs in pregnancy. Ontario Association of Family Physicians.
- 175) June 1996: San Diego, Cal.: "Drugs in pregnancy; industry academia collaboration". 32nd meeting of the Drug Information Association.
- 176) July 1996: Chicago, Il: Therapeutic drug monitoring in neonates. Amer Academy of Clin. Chemistry.
- 177) November 1996: Toronto, Ont.: Ontario Association of Family Physicians: Drugs in Pregnancy.
- 178) December 1996: Toronto, Ont.: 2nd Provincial Conference on Fetal Alcohol Syndrome and Effects: Motherisk approach.
- 179) December 1996: Montreal, Queb.: Toxicology Society of Canada: Drugs in pregnancy.
- 180) January 1997: Tel Aviv, Israel: Association of Clinical Biochemistry: Therapeutic Drug Monitoring.
- 181) January 1997: Department of Medicine, Tel Aviv University, Kefar Saba Hospital: Drugs in Pregnancy.
- 182) March 1997: San Diego, Cal.: American Society for Clinical Pharmacology & Therapeutics: "Bias against the null hypothesis in maternal fetal toxicology".
- 183) April 1997: Hamilton, Ont: The Canadian Pharmacoepidemiology Forum. Bias against negative results.
- 184) May 1997: Indianapolis, Global Health Convention: Antidepressants in Pregnancy.
- 185) May 1997: Washington, DC: The Society for Pediatric Research. EMLA for circumcision pain.
- 186) June 1997: Halifax, NS: The Society of Obstetrics & Gynecology of Canada: Drugs in pregnancy.
- 187) June 1997: Vancouver, BC: Child Health 2000: Environmental toxins in pregnancy.
- 188) September 1997: Washington, DC: The New York Academy of Sciences: Cocaine effects in pregnancy.
- 189) November 1997: Cleveland, OH: The Cleveland Hospitals. Antidepressant drugs in pregnancy.

- 190) October 1997: Rio de Janeiro: The Neuropsychopharmacology Society of Brazil: Antidepressants in pregnancy.
- 191) November 1997: Vancouver, BC: The International Society of TDM: Biological markers of intrauterine exposure to drugs.
- 192) January 1998: Toronto, Ont.: The Air Children Breathe. Pollution Probe.
- 193) February 1998: Regina, Sask.: The POGO annual meeting for physicians & nurses: The Children of Neverland.
- 194) March 1998: Whistler, BC: The International Conference of Emergency Medicine: Drugs in pregnancy.
- 195) March 1998: Sault Ste. Marie, Ont.: Effects of Alcohol in Pregnancy.
- 196) April 1998: Niece, France: Pain in the neonate consensus meeting: Topical Analgesia.
- 197) April 1998: Budapest, Hungary: Hungarian Association of Psychiatry: Antidepressants in Pregnancy.
- 198) June 1998: Boston, Mass.: Drug Information Association: Drugs in Pregnancy.
- 199) September 1998: Copenhagen, Danemark: European Society of Psychiatry. Antidepressants in Pregnancy.
- 200) October 1998: Toronto, Ont.: International Conference on Hair-Drug testing: Testing drugs in neonates.
- 201) October 1998: San Francisco, CA: American Academy of Pediatrics: Drugs in breastfeeding.
- 202) October 1998: Vancouver, BC: University of BC OBG-Family Practice Annual Day: Drugs in Pregnancy.
- 203) October 1998: Toronto, Ont.: First International Conference on NVP.
- 204) November 1998: Quebec City: Annual meeting of Society of Clinical Chemistry of Quebec: Biological markers of drug exposure in the neonate.
- 205) November 1998: Halifax, NS: Shoppers Drug Mart Pharmacists: Folic acid in pregnancy.
- 206) November 1998: Calgary, Alberta: Shoppers Drug Mart Pharmacists: Folic acid in pregnancy.
- 207) February 1999: Tel Aviv, Israel: Sheba Medical Center: New frontiers in pediatric pharmacology.

- 208) February 1999: Banff Alberta: Canadian College of Family Physicians: Treatment of NVP.
- 209) March 1999: Maui, Hawaii: North American Association of Psychosocial Obstetrics: Antidepressant drugs in pregnancy.
- 210) March 1999: Moncton, NB: Moncton General Hospital Neonatal Unit: Illicit drug exposure in pregnancy.
- 211) March 1999: Vancouver, BC: Westminster General Hospital: Fetal Alcohol Syndrome.
- 212) March 1999: Prince George, BC: Prince George General Hospital: Fetal Alcohol Syndrome.
- 213) April 1999: Halifax, NS: Dalhousie University. The Peter E. Dressel Memorial Lectureship in Pharmacology.
- 214) April 1999: Boston: Harvard University: Annual course in teratology: (1) organic solvents in pregnancy, (2) epidemiological considerations.
- 215) May 1999: Calgary, Alberta: Fetal Alcohol Syndrome Convention: The Motherisk alcohol line.
- 216) August 1999: Baden, Austria: International consensus group for pain in the neonate.
- 217) September 1999: Montreal, QC: Royal College meeting: Perception of teratogenic risk by women.
- 218) September 1999: Toronto: American Society for Reproductive Medicine. Exposure to antidepressants in pregnancy.
- 219) October 1999: Detroit, Michigan: NIH planning meeting on Nausea and Vomiting of pregnancy.
- 220) March 2000: Cleveland, Ohio: Rainbow & Babies Hospital: Biological markers of intrauterine exposure to drugs.
- 221) March 2000: Los Angeles, California: American Society of Clinical Pharmacology and Therapeutics Meeting. Issues with drug compliance.
- 222) March 2000: Los Angeles, California: American Society for Clinical Pharmacology: Renal tubular mechanisms of drug handling.
- 223) April 2000: London, Ontario: Children's Hospital: Do neonates remember neonatal pain?
- 224) April 2000: London, Ontario (UWO): Renal handling of drugs: opening the black box.

- 225) May 2000: Detroit, Michigan: Children's Hospital Residents Round: Tenfold errors in drug doses.
- 226) June 2000: Boca Raton, Fla: Teratology Society. Herbal products in pregnancy.
- 227) July 2000: Detroit, Michigan: Children's Hospital Grand Rounds: Drugs in pregnancy: Treating the mother, protecting the unborn.
- 228) September 2000: Washington, DC: International Nausea and Vomiting in Pregnancy: US vs Canadian experience.
- 229) September 2000: Washington, DC: NIH Meeting on Nausea and Vomiting in Pregnancy.
- 230) September 2000: Washington, DC: FDA Pregnancy Labeling Committee: Motherisk approach to counseling.
- 231) October 2000: Kelowna, BC: BC College of Family Physicians: Drugs in pregnancy-an update.
- 232) November 2000: Toronto, Ontario: Medical Information Group of the Rx/R&D: Drugs in pregnancy update.
- 233) November 2000: Toronto, Ontario: Innovus Workshop on drug trials in children: Interaction with the American Centers.
- 234) November 2000: Long Island NY: Northshore Hospital (Dr. A. Hershlag): Drugs in Pregnancy.
- 235) December 2000: Washington, DC: NIH/FDA Conference: Clinical Pharmacology in Pregnancy: The interface of Clinical Pharmacology and Fetal Safety.
- 236) January 2001: Dalhousie University, Halifax, NS: IWK Grand Rounds: Do children remember circumcision pain?
- 237) February 2001: Ottawa, Ont.: CIHR: Network of Canadian Pediatric Pharmacology.
- 238) February 2001: Mont Tremblant, Quebec: Canadian Rheumatology Association: Drugs in Pregnancy.
- 239) February 2001: Toronto: Drug Information Association: The Mother-Net.
- 240) March 2001: Berlin: 1st World Congress of Women's Mental Health: Antidepressant Drugs in Pregnancy.
- 241) April 2001: Bethesda, MD: NIH: Adverse Drug Reactions in Children. Renal handling of drugs.
- 242) April 2001: Ottawa, Ont.: Ethical Framework of Drug Trials in Children. Canadian Ped Society Bal Fetal Drug Therapy.

- 243) April 2001: Ottawa, Ont.: Ethical Framework of Drug Trials in Children. Canadian Ped Society. Pediatric Subpopulations: Case presentation and discussion.
- 244) April 2001: Baltimore, MD: Society for Pediatric Research: Ethical dilemmas in children: Voluntariness of children.
- 245) April 2001: Dept. of Medicine, Dalhousie University, Halifax NS: Treating the Mother-Protecting the Unborn.
- 246) May 2001: Gander, Newfoundland: First provincial meeting on FAS: Prevention and diagnosis of FAS.
- 247) May 2001: Gander, Newfoundland: First provincial meeting on FAS: The Motherisk Program.
- 248) May 2001: Calgary, Alberta: Faculty of Medicine Biological markers of intrauterine exposure to drugs.
- 249) June 2001: Quebec City: Creating a CME for Drugs in Pregnancy (Chairperson).
- 250) June 2001: Washington, DC: American Society for Clinical Pharmacology & Therapeutics: Pediatric Pharmacology, Medication Misadventures.
- 251) August 2002: Toronto, Ont.: Arthritis consumer experts: Chloroquine in pregnancy.
- 252) August 2001: Toronto, Ont.: CIHR Institute of Genetics: Clinical Genetics Research Workshop: Common pitfalls in clinical studies.
- 253) September 2002: Washington, DC: International association of therapeutic drug monitoring and clinical toxicology: Biomarkers of drug exposure during pregnancy.
- 254) September 2001: Toronto, Ont.: 2nd Annual Fetal Alcohol Syndrome Annual Day, Motherisk Program. Overview of critical issues.
- 255) September 2001: Paris, France: 3rd Socity of Research in Nicotine and Tobacco. Nicotine replacement therapy in pregnancy.
- 256) October 2001: Kamloops, BC: BC Reproductive Care Program: Better Beginnings – Motherisk prevention and diagnosis of FAS.
- 257) October 2001: Kamloops, BC: Drug exposure during pregnancy and lactation.
- 258) October 2001: Minett, Ont.: The Ontario Coalition of CPAC and CPNP Projects: Fetal Alcohol Syndrome: Diagnosis and Prevention.
- 259) November 2001: Limassol, Cyprus: The European Society for Dev. Pharmacology: Drugs in pregnancy: The real, unreal and surreal.

- 260) December 2001: Petach Tikva, Israel: Schneider National Children's Hospital: State of the art of Pediatric Drug Therapy.
- 261) January 2002: Houston, TX: OTID research meeting: Ethics of drug research in pregnancy.
- 262) February 2002: Long Island, NY: Northshore Hospital (Dr. A. Hershlag): Drugs in Pregnancy.
- 263) April 2002: Toronto, ON: Pediatric Update, The Hospital for Sick Children. 1) Drugs in pregnancy-suffer the children. 2) Critical appraisal of scientific papers.
- 264) April 2002: Rockville, MD: FDA/CDER: Perception of teratogenic risk. Visiting Professor.
- 265) April 2002: Bethesda, MD: NIH: Workshop on chemicals and drugs in breastmilk. Counseling nursing mothers taking medication.
- 266) April 2002: Kelowna B.C.: Society for rural physicians of Canada. Diagnosing FASD.
- 267) May 2002; Peterborough, Ont: Department of Health: Chemical exposure in pregnancy.
- 268) June 2002: Toronto, Ont: Canadian Pediatric Society 3rd Annual Meeting. Drug exposure in pregnancy.
- 269) June 2002: San Francisco, CA: Fetal-Alcohol-Canadian Expertise, 2nd Annual Meeting. Chair and presenter of Motherisk Experience.
- 270) September 2002: Muskoka, Ont: CAPC Annual Meeting: Diagnosing FASD.
- 271) September 2002: Vancouver B.C.: Fetal Alcohol Day: Diagnosing FASD.
- 272) September 2002: Vancouver B.C.: Drugs in pregnancy. Workshop for physicians.
- 273) October 2002: Liege, Belgium: European Society for Developmental Pharmacology: Global Consortium of Pediatric Pharmacology.
- 274) October 2002: Essen, Germany: Society for Prevention of Tobacco Induced Disease, 1st Meeting. 1) NRT in pregnancy. 2) Bupropion in pregnancy.
- 275) October 2002: Ottawa, Ont: The Ottawa Hospital, Department of OB/GYN: Drugs in pregnancy.
- 276) November 2002: Tel Aviv, Israel: The Unborn Child-Scientific Discovery, Medical and Ethical Issues", "Drugs in Pregnancy".
- 277) January 2003: Houston, TX: OTIS Research meeting: Acutane in pregnancy.

- 278) March 2003: Washington, DC: American Society for Clinical Pharmacology & Therapeutics: International symposium: Issues of drugs in pregnancy.
- 279) Ontario Meeting on FASD: The Motherisk Approach.
- 280) May 2003: Tel Aviv, Israel: "Art therapy for children". The Israeli Society for Developmental Pediatrics. The Bear Theatre.
- 281) May 2003: Zerifin, Israel: Pediatric Grand Rounds Systemic exposure to morphine and sickle cell crisis.
- 282) May 2003: Owen Sound, ON: FASD diagnostic training.
- 283) June 2003: Fort Lauderdale, CA: FACE meeting: Fetal Alcohol Canadian Expertise.
- 284) June 2003: Philadelphia: Teratology – OTIS meeting: Accutane in pregnancy.
- 285) June 2003: Sioux Lookout: FASD diagnostic training.
- 286) August 2003: Ottawa, ON: Health Canada diagnostic task force on FASD.
- 287) September 2003: Rome, Italy: International Association of Pediatric Laboratory Medicine: Biomarkers of drug exposure in pregnancy.
- 288) September 2003: Ottawa, ON: 25th Anniversary of Canadian Society for Clinical Pharmacology. Symposium: The future of Clinical Pharmacology in Canada.
- 289) October 2003: Winnipeg: International Society for Tobacco Induced Disease 2nd Congress "Smoking in Pregnancy".
- 290) November 2003: Toronto, ON: Ontario College of Family Physicians: Drugs in Pregnancy.
- 291) November 2003: Ottawa, ON: First Canadian Drug Information Association Meeting: Drugs in Pregnancy.
- 292) November 2003: Winnipeg: The Northwest Convention of FAS: Meconium Analysis for FAS.
- 293) November 2003: Toronto, ON: Motherisk Update: Accutane in Pregnancy.
- 294) November 2003: Toronto, ON: Motherisk Update: Diagnosis of FAS.
- 295) December 2003: Toronto, ON: Street Women and FAS Convention. The Children of Neverland.
- 296) January 2004: Salt Lake City:
- 297) January 2004: Toronto, ON: FASD Workshop First Nations.

- 298) February 2004: Ottawa, ON: Diclectin Dosing
- 299) March 2004: Hamilton, ON: CAS (Children's Aid Society): Measuring drugs in neonates.
- 300) March 2004: Miami, FL: ASCPT (American Society for Clinical Pharmacology & Therapeutics) Congress.
- 301) March 2004: Rockville, MD: NICHD SEP Review Study Session.
- 302) April 2004: Prague : ENTIS Talk
- 303) April 2004: Providence, RI: Grand Rounds (Obstetric Medicine – Brown's University).
- 304) May 2004: London, ON: Royal Victoria Hospital: Drugs in Pregnancy.
- 305) May 2004: London, ON: Rounds at London-Med University Hospital.
- 306) May 2004: North Bay, ON: FASD Workshop.
- 307) May 2004: London, ON: Drug Therapy Day (Talk in smoking cessation in pregnancy and panel for Pediatrics).
- 308) June 2004: Winnipeg, MB: Therapeutic Congress. Pain management in children.
- 309) June 2004: Vancouver, BC: Teratology Society: Treating the Mother-Protecting the Unborn.
- 310) November 2004: Toronto: POGO: Chemotherapy for neonatal cancer.
- 311) November 2004: Beer Sheba Israel: Israeli Society for Clin. Pediatrics: Pharmacology of Pain in Children.
- 312) November 2004: Montreal: Quebec Association of Rheumatologists: Treating rheumatologic conditions in pregnancy.
- 313) November 2004: Yellowknife: Yellowknife Public Health Unit: Diagnosis of FASD.
- 314) November 2004: Yellowknife: Yellowknife General Hospital Grand Rounds: Drug therapy in pregnancy.
- 315) December 2004: Montreal, Quebec: CIHR Workshop in Toxicology: Perception of teratogenic risk by women.
- 316) December 2004: Montreal, Quebec: CIHR Workshop in Toxicology: Drug exposure during pregnancy.
- 317) June 2004: Vancouver, BC: Fetal Alcohol Canadian Expertise: Chairing the meeting.

- 318) September 2004: Saskatoon: Fetal Alcohol Canadian Expertise 5th round table: Toward behavioral phenotype of FAS.
- 319) September 2004: Regina, SK: FACE Meeting: Diagnosing FASD.
- 320) June 2004: Essen, Germany: European Society for Developmental Pharmacology: Health economical implications of pediatric pharmacology.
- 321) May 2004: Prague: European Society fo Teratology Information Services – Nato Symposium. Cancer chemotherapy in pregnancy.
- 322) May 2004: Prague: European Society of Teratology Information Services – Nato Symposium. Perception of teratogenic risk.
- 323) April 2004: Rhode Island: Brown's University. Visiting professorship: Drug therapy during pregnancy.
- 324) May 2004: London, ON: Victorial Hospital, Grand Rounds: Drugs in pregnancy.
- 325) May 2004: London, ON: St. Joseph's Hospital,Grand Rounds: Drugs in pregnancy.
- 326) June 2004: London, ON: London, ON Health Science Centre: Drugs in pregnancy.
- 327) October 2004: London, ON: Children's Hospital of Western Ontario Grand Rounds: Opioid for pain in children.
- 328) January 2005: Scottsdale, AZ: OTIS Research Meeting: Health Economy of TIS.
- 329) January-March 2005: (3 sessions): Toronto, ON: Children's Aid Society: Diagnosis of FASD.
- 330) April 2005: Vancouver, BC: Canadian Therapeutic Forum: The status of Pediatric Pharmacology.
- 331) April 2005: Vancouver, BC: Women's Hospital, Dept. of OBGYN Grand Rounds: Fetal Alcohol Spectrum Disorder.
- 332) April 2005: Louisville, KY: International Association of Therapeutic Drug Monitoring & Clinical Toxicology meeting. Round Table: Therapeutic drug monitoring in breastfeeding.
- 333) June 2005: Santa Barbara, CA: Fetal Alcohol Canadian Expertise meeting.
- 334) June 2005: Santa Barbara, CA: FAS Study Group: Digital measurement of morphometry in diagnosing FASD.
- 335) June 2005: St. Pittsburgh, FL: OTIS – Teratology meeting. Symposium: Reproductive Toxicology of Organic Solvents: The knowledge, the gap.

- 336) June 2005: Hamilton, ON: Catholic Children's Aid. Neonatal hair and meconium for drugs and alcohol.
- 337) February 2005: Washington, DC: OPRU Meeting, NICHD.
- 338) February 2005: Barcelona, Spain: Drugs in pregnancy; - Fetal Alcohol Syndrome biological markers. University of Barcelona, DiMar Hospital.
- 339) February 2005: Barcelona, Spain: Novartis: Global Epidemiology. Drugs in pregnancy.
- 340) March 2005: Ottawa: Health Canada: FASD Diagnosis.
- 341) April, 2005: Washington, DC: OPRU meeting, NICHD.
- 342) April 2005: Vancouver, BC: Paediatric Clinical Pharmacology Challenges and Opportunities Symposium.
- 343) June 2005: St. Petersburgh, FL: OTIS Annual Meeting: Organic solvents in pregnancy.
- 344) June 2005: Vancouver, BC: Teratology Society Annual Meeting.
- 345) July 2005: Montreal, QC: NIH-CIHR. Summer Institute of Obstetric Pharmacology, Course Coordinator.
- 346) September 2005: Edmonton, AB: Edmonton Health Region Pharmacists: Drugs in Pregnancy.
- 347) September 2005: Montreal, Quebec: 36th Annual Meeting: International Society of pharmaneuuroendocrinology: Biological markers of intrauterine drug exposure.
- 348) October 2005: Newfoundland: Canadian Association of Pediatric Health Centers. Fetal Alcohol Spectrum Disorder.
- 349) October 2005: Ottawa: IHDCYH Strategic Plan Review, CIHR.

EDUCATIONAL FILE

A. **Regular Teaching:**

- 1) 2nd year medicine - Pharmacology. Developmental Pharmacology & Toxicology; drug interactions, New Frontiers; (Since 1989).
- 2) 3rd year medicine - Clinical Pharmacology. Drug Compliance; (Since 1988).
- 3) Department of Pharmacology - Graduate course in Clinical Pharmacology (PCL 1004), course developer and coordinator (Since 1989).

- 4) 3rd year medicine - Pediatrics; Teaching pediatric skills, (Since 1986).
- 5) 4th year medicine - Pediatrics; Teaching pediatric clerks as Ward Chief, (Since 1986).
- 6) 4th Pharmacy - Clinical Pharmacy; Clinical Teratology, (Since 1986).
- 7) Graduate Pharmacy: Therapeutic Drug Monitoring Digoxin, (Since 1986).
- 8) PCL 473 - Interdisciplinary Toxicology (since 1993).

B. Supervision of Graduate Students:

1. **Department of Pharmacology:** (Year of graduation)
Karen Graham (graduated 1990) - Cocaine in the fetus (U of T open).
Dr. Monica Bologa (1990) - Drug metabolism in pregnancy (MOH).
Rachel Forman (1992) - Fetal exposure to cocaine (U of T open).
Lydia Derwelany (1992) - Placental drug transfer.
Dr. Kathleen Shilalukey (1993) - Theophylline in children (WHO).
Shannon Stobie (1993) - L₁ Kinetics.
Carmine Simone (1993); presently PhD student. - Placental cocaine transfere (MRC).
Donna Zemlickis (1993) - Cancer in pregnancy.
Cindy Woodland (1999) - Renal handling of drugs (CF foundation).
Dr. Richard Haynes (1993) - Kinetics in children.
Anne Pastuszak (1994) - Retinoids in pregnancy (U of T open & Cannaught).
Chrisoula Eliopoulos (1994) - Hair accumulation of nicotine (MRC).
Dr. Elena Pope (1995) - L₁ kinetics (MRC-Industry).
John Rogan (1997) - Amlodipine in children (Pfizer).
Myla Moretti (1996) - Drugs in breastmilk.
Kristen McMartin (1996); presently PhD student. - (U of T open).
Paulo Mazzotta (1997) - Pharmacology of morning sickness (Industry Duchesnay).
Natalie Kulin (1997) - Depression in pregnancy.
Dr. Aleksandra Pastrakuljic (2003) - RestraCom.
Amy Chan (1997) (with S. Ito) - Drugs in breast milk (Motherisk fund).
Katarina Alekxa (present) - Renal drug handling (MRC).
Amy French (2003) - *In utero* malignancy and drug/nutrient exposure.
Natasha Pinto (2004) - Ontogeny of P-gp in the kidney.
Brian Chan (2003) - Bupropion in pregnancy.
Daphne Chan (2003) - FAEE and FAS.
Jennifer Kraemer (2005) - Placental P-gp.
Kate McKenna (2004) - Antipsychotics in pregnancy.
Eric Ahn (present) - Pregvit in pregnancy.
Patricia Nguyen (present) - Pregvit in pregnancy.
Sanjog Kalra (present) - Cortisol and depression
Christelle Gedeon (present) - Placental perfusion of glyburide.
Brittany Sauve (present) - Corticosteroids in pregnancy.
Diana Stempak (present) - Antiangiogenic therapy for pediatric tumors.
Rebecca Hancock (present) - Neonatal ____?

2. *School of Pharmacy:*

- Anne Taddio (1997) - Pain in the neonate (U of T open & other).
Arnold Seto (1992) (with T. Einarsen) - H₁ blockers in pregnancy.
Edith St. Pierre (1995) - Daunarubycin in children (Motherisk fund).
Franka Grilli (2000) - Detection of cocaine in hair (part time student).
Colleen Duncan (2000) - Motherisk counseling process (part time student).
Ernest Kopecky (1999) - Transplacental morphine (Industry).
Marry Chu (1996) - Cyclosporine adverse effects (Motherisk).
Marjie Hard (1998-2003) - Etiology of FAS (NSERC).
Matthew Wong (1998-2000) - HIE in pregnancy
Samar Shuhaibar (2000-2002) - Anesthetics in pregnancy.
Lori Bonari (2003) - Depression in pregnancy.
Lisa O'Brien (2001-2004) - Amitop for pain in neonates.
Charlene Ho (2002-2004) - Analgesia in neonates.
Anna Sivolejesova (present) - Drugs in pregnancy.
Moumita Sarkar (present) - Alcohol in pregnancy.
Ingrid Goh (present) - Fetal alcohol spectrum disorder.

3. *Institute of Medical Sciences:*

- Nancy Ondrusek (1994) - Ethics of drug research in children (part time).
Frank Fassos (1997) - L₁ kinetics & dynamics (MRC-Industry).
Anne Pastuszak (present) - Evidence in maternal fetal toxicology.
Brenda Stade (present) - Economic burden of FAS (RestraCom).
Dr. Mariam Fouladi (2002) - Amifostine kinetics.
Leslie Born (2004) - Dysphoria in women (MRC).
Dionne Laslo (present) - Organic solvents in pregnancy.
Dr. Bikul Das (present) - Oncopharmacology.
Phillip Blanchette (2005) - Smoking in pregnancy.
Lisa O'Brien (present) - Depression in pregnancy.

4. *University of Western Ontario (Physiology-Pharmacology)*

- Nancy Chen - Developmental nephrotoxicity.

C. *Supervision of Postdoctoral Fellows:*

- Dr. David Long (UK) - (until 1986) - Maternal-fetal toxicology.
Dr. Jacob Feldman (Israel) - (1987) - Maternal-fetal toxicology.
Dr. Christine Hermann (USA) - (1990) - L₁ trials (MRC).
Dr. Monica Bologa (Canada) - (1992) - Maternal-fetal toxicology (MOH).
Dr. Yedidia Bentur (Israel) - (1990) - Pediatric toxicology (MOH).
Dr. David Johnson (USA) - (1991) - Pediatric pharmacology (MOH).
Dr. Isabelle Robieux (France) - (1992) - Pediatric pharmacology (French MRC).
Dr. Elliahu Zalstein (Israel) - (1989) - Pediatric Pharmacology-cardiology (MOH).
Dr. Maurice Levy (Canada) - (1990) - Pediatric pharmacology (MOH).
Dr. Gianmario Ferrazini (Switzerland) - (1990) - 6-MP kinetic-dynamic (Swiss grant).
Dr. Shinya Ito (Japan) - (1995) - Membrane-transport (RestraCom/MRC).
Dr. Irena Nulman (Israel) - present - FAS research (Motherisk).
Dr. Prashant Joshi (Canada) - (1994) - Pediatric pharmacology (MOH).
Dr. Doreen Matsui (Canada) - (1993) - L₁ trials (MOH).

- Dr. Jeff Tyberg (Canada) - (1993) - Clinical Toxicology (MOH).
Dr. Lyla Warif - (Canada) - (1993) - Maternal-fetal toxicology (Motherisk).
Dr. Laura Magee - (Canada) - (1994) - Maternal-fetal toxicology (MOH).
Dr. Izhar Qamar - (US) - (1994) - Pediatric Pharmacology (MOH).
Dr. Robert Lau (Canada) - (1994) - Pediatric pharmacology (MOH).
Dr. Pascale Burtin (France) - (1994) - Pediatric pharmacology (French MRC).
Dr. Douglas Blowey (US) - (1996) - Renal handling of drugs (Kansas City grant).
Dr. Abhya Gupta (Canada) - (1997) - Pediatric pharmacology (MOH, Can Soc Clin Pharm)
Dr. Dhurbasa Chattergoon (Trinidad) - (1996) - Pediatric Pharmacology (MOH).
Dr. Elena Pope (Romania) - (1996) - L₁ trials (MRC-industry).
Dr. Ileana Moncica (Romania) - (1995) - Pediatric hypertension (Pfizer).
Dr. Jochen Theis (Germany) - (1996) - Pediatric pharmacology (German MRC).
Dr. Shlomit BenDavid (Israel) - (1995) - Maternal-fetal toxicology (Motherisk).
Dr. Jennifer Knight (Jamaica) - (1994) - Nicotine in children (MOH).
Dr. Candice Rowe (Canada) - (1996) - Pediatric pharmacology (MOH).
Dr. Sohail Khattak (Canada) - (1998) - Organic solvents in pregnancy (MOH).
Dr. Anil Hinaria (India-Canada) - (1996) - Pediatric pharmacology (Motherisk).
Dr. Madlen Gazarian (Australia) - (1996) - Rheumatology-pharmacology.
Dr. Ronen Loebstein (Israel) - (1998) - L₁ trials (MRC-industry).
Dr. Debbie Kennedy (Australia) - (1997) - Maternal-fetal pharmacology (Motherisk).
Dr. Benoit Bailey (Canada) - (1997) - Pediatric pharmacology - (MOH).
Dr. Arieh Lalkin (Israel) - (1998) - Clinical toxicology (Motherisk).
Dr. Orna Diav-Citri (Israel) - (1998) - L₁ trials (MRC-industry).
Dr. Svetlana Emiljanova (Canada) - (2000) - Maternal-fetal toxicology (Motherisk).
Dr. Vladimir Karaskov (Canada) - (1998) - Pediatric pharmacology (Sanzoz).
Dr. Savithiri Rathnапalan (Saylon, Canada) - (1997) - Pediatric pharmacology (MOH).
Dr. Raafat Bishai (Egypt, Canada) - (1999) - Nausea & vomiting of pregnancy (Duchesnay).
Dr. Reza Moienafshari (Iran) - (1999) - Pediatric pharmacology (Motherisk).
Dr. Benny Bar Oz - (Israel) - (1999) - Neonatal pharmacology (RestraCom).
Dr. Richard Hackman (Syria) - (2000) - Nicotine patch in pregnancy (Motherisk).
Dr. Sunita Vohra (Canada) - (1999) - Drug trial methodology (MOH).
Dr. Tommy Ho (Canada) - present - Pediatric-pharmacology (Can Soc. Clin. Pharmacol).
Dr. Gil Klinger (Israel) - (2000) - Maternal-fetal toxicology (RestraCom).
Dr. Gordana Atanackovic (Yugoslavia) - (2000) - Nausea and vomiting in pregnancy (Duchesnay).
Dr. Zina Levichek (Russia) - 2002 - Perinatal Pharmacology (Motherisk).
Dr. Meena Pole (India) - 2001 - Maternal-fetal toxicology (Motherisk).
Dr. Massoud Rezvani (Iran) - Present - Pediatric Pharmacology.
Dr. Dick Oepke (Netherland) - (2000) - Nausea and vomiting in pregnancy (Duchesnay).
Dr. Chris Parshuram (Australia) - 2003 - Pediatric pharmacology (HSC).
Dr. Adriana Costei (Romania) - 2003 - HIV in pregnancy (Motherisk).
Dr. Alexander Liaschko (Russia) - 2001.
Dr. Eran Kozer (Israel) - 2002 - Pediatric pharmacology (Motherisk).
Dr. Yaron Yagev (Israel) - 2001 - Occupational exposures in pregnancy.
Dr. Lillian Sung (Canada) - 2004 - (with Dr. Brian Feldman): N of 1 studies in children.

Dr. Naomi Halachmi (Israel) – 2003 – Ontogeny of renal drug metabolism.
Dr. Rada Boskovic (Bosnia) – present – Drugs in pregnancy.
Dr. Raanan Cohen-Kerem (Israel) – 2004 – Drugs in pregnancy.
Dr. Serghei Gargau (Russia) – 2004 – Drugs in pregnancy.
Dr. Ibrahim Fayed (Egypt) – 2004 – Clinical Pharmacology.
Dr. Marina Avner (Israel) – 2005 – Developmental Pharmacology.
Dr. Charlene Pivko (Switzerland) – 2004 – Pharmaco-economics.
Dr. Yaron Finkelstein (Israel) – present – Restracom.
Dr. Tali Finkelstein (Israel) – present
Dr. Alejandro A. Nava-Ocampo (Mexico) – 2004 – Maternal-fetal pharmacology.
Dr. Han Yeol Jung (Korea) – 2004 – Maternal-fetal pharmacology.
Dr. Tali Schechter (Israel) – present – Pediatric oncopharmacology.
Dr. Alon Shrim (Israel) – present – Maternal-fetal pharmacology.
Dr. Facundo Garcia-Bourssien (Argentina) – present – Developmental pharmacology.
Dr. Alaa Ali (Egypt) – 2005 – Perinatal pharmacology.

D. **Supervision of The Undergraduate Project Course in Pharmacology/Toxicology (PCL 472, PCL 47Y)**:

Ten students each academic year (since 1986).

E. The Arts and Science of Clinical Medicine II. 1986-96

F. The MSc Program in Genetic Counselling: Concepts in Clinical Genetics (MMG 12264):
Pharmacogenetics. 1999 –

G. “Membrane Transport” graduate course: (JFK 1122H). 1994 -

H. “Clinical Toxicology” graduate course (JNP 1016S). 1999 -

I. Graduate Seminars in toxicology (JNP1016S). 2003 -

J. Pharmaepidemiology (PHM 1118). 1999 -

I. **International:**

1. The International Network of Training Programs in Pediatric Pharmacology. Founder
and coordinator (see under Books, No. 3).

2. Training program in Clinical Toxicology: Coordinator of the Toronto program (one of
15 approved by The American Academy of Clinical Toxicology), (until 1996).

3. Director: University of Toronto Program in Clinical Pharmacology.

EDUCATIONAL INNOVATIONS:

- 1) Created and continuously improves the U of T course in Clin. Pharmacology (PCL 1004).
- 2) Created the program "Awakening" to teach Clin Pharmacology (published in Clin, Pharmacol Ther).

- 3) Created the International Network of Pediatric Pharmacology Training Program (published as a book).
- 4) Created Motherisk Update for CME of family physicians (published monthly in Can. Family Physician).
- 5) Created Motherisk Website (www.motherisk.org) as CME for OBGYN (with support of SOGC).
- 6) Created a course in critical appraisal of drug studies in children (every Thursday at 10:00 a.m.).
- 7) Created a program to identify and improve tenfold medication errors by pediatric residents.
- 8) Created the International Diploma in Pediatric Pharmacology.

CHILDREN'S BOOKS

- 1) G. Koren: "*Shubi Dubi Tales*". Sifriyat Poalim Pub. Comp. Tel-Aviv, 1979.
- 2) G. Koren: "*Journey to Noteland*". Or-tav Pub. Comp. Tel-Aviv, 1980.
- 3) G. Koren: "*Touti is Ill*". Sifriyat Poalim Pub. Comp. Tel-Aviv, 1981.
- 4) G. Koren: "*Israeli Children Street Songs*". Dalia Peled Pub. Comp. Tel-Aviv, 1982.
- 5) G. Koren: "*Pediatric Ward*". Dalia Peled Pub. Comp. Tel-Aviv, 1982.
- 6) G. Koren: "*Pictures Telling Stories*". A series of 16 books. Yavne Pub. Comp. Tel-Aviv, 1982.
- 7) G. Koren: "*Books To Those We Love*". First 4 books out of 8. Yavne Pub. Comp. Tel-Aviv, 1982.
- 8) G. Koren: "*Pitzimouse I*". Or-tav Pub. Comp. Tel Aviv, 1985.
- 9) G. Koren: "*Pitzimouse II*". Or-tav Pub. Comp. Tel Aviv, 1987.
- 10) G. Koren: "*Get Well Soon*". Kidfest Ltd., New York, 1988.
- 11) G. Koren: "*Shoobi Doobi Bear*". Kidfest Ltd., New York, 1988.
- 12) G. Koren: "*Pitzimouse III*". Or-tav Pub. Comp. Tel Aviv, 1988.
- 13) G. Koren: "*Books To Those We Love*". Books 5-8 out of 8. Yavne Ltd., Tel Aviv, Israel 1990.
- 14) G. Koren: "*Pitzimouse IV*". Or-tav Pub. Comp. Tel Aviv, 1991.

- 15) G. Koren: "*The Time Turtle*". Tarbuton Ltd, Tel Aviv, Israel, 1992.
- 16) G. Koren: "*Tails-A Fairy Tale on Furry Tails*", The Kid In Us Publications, Toronto, 1992.
- 17) G. Koren: "*A Medical Encyclopedia for Children*". Yavne Ltd, Tel Aviv, Israel, 1992.

MUSIC

GK created over 50 musical albums, for both adults and children, in Israel. The album "Tails" was released in Toronto in 1993.

CHILDREN'S PLAYS

- 1) "Shubi Dubi Tales": Orot Ltd., Tel Aviv 1978-80.
- 2) "Zalman" - Israeli Children's Street Songs": TEDI productions, Tel Aviv 1980-83.
- 3) "The Journey to Noteland": University of California, Children's Theatre Dept. 1986-87.
- 4) "Tails": The Bear Theatre, The Hospital for Sick Children, Toronto 1992 -
(also performed in Miller's Children Hospital of Long Beach California and in Shneider National Children Center in Petah Tiqwa, Israel).

**APPENDIX 2
(Gervais Declaration)**

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date set forth below as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
Date of Signature
and Deposit: 10/12/06 Nicole H. Vargas

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Duchesnay Inc.
Serial No.: 10/611,803
Filed: July 1, 2003
Title: PHARMACEUTICAL DOSAGE FORM BEARING PREGNANCY-FRIENDLY INDICIA
Examiner: Hawes, Pili Asabi

DECLARATION UNDER 37 CFR 1.132

Dear Sir:

I, Eric Gervais, of the City of Laval, Canada, being duly sworn, **MAKE OATH AND SAY AS FOLLOWS:**

1. This Declaration sets forth my opinion relating to this matter and the basis for my opinion.
1. **EXPERIENCE AND QUALIFICATIONS**
2. I have been the Executive Vice-President of Duchesnay Inc. since 1994.
3. Created before 1970 to distribute over-the-counter and prescription medications to Quebec pharmacies, Duchesnay Inc. underwent a change of orientation around 1991, becoming the first pharmaceutical company to dedicate itself exclusively to the pregnant women and their newborn, to ensure that expecting women who require pharmacological treatments for pre-existing or pregnancy-related diseases have

access to proper counselling and to medications that are proven safe for them and for their newborns. Since then, Duchesnay has been evolving as a research-based pharmaceutical company with the vision to improve women's quality of life of women during pregnancy and lactation while reducing the number of birth defects and Impacts on their newborns.

4. Thus, I have more than 12 years of experience in leading a company dedicated to pregnant women's health, as well as in associated research and development.
 5. I am also an inventor in several patents and patent applications in the name of Duchesnay Inc.
 6. I am one of the inventors of United States Patent Application 10/611,803.
- II. **DICLECTIN®**
7. Diclectin® comprises doxylamine succinate and pyridoxine hydrochloride as active ingredients. In Canada, it is the only anti-nauseant and anti-vomiting medication specifically indicated, prescribed and labelled for the management of NVP (nausea and vomiting of pregnancy) at any stage of pregnancy. It is sold in the form of unit bottles comprising 100 tablets each.
 8. Diclectin® was first launched on the Canadian market in 1975.
 9. Throughout the recent years, the percentage of yearly increase of sales of unit bottles of Diclectin® was generally decreasing from year to year in Canada as a whole, as per the below table. Such tendency was not expected to change.

1998-1999	1999-2000	2000-2001	2001-2002
18%	11.7%	9.4%	8.6%

10. It is to be noted that, since Diclectin® is the only available prescription medicament for NVP in Canada, Duchesnay is the only company in this particular field. Thus an

increase in the sales of unit bottles of Diclectin® is directly linked to an increased number of pregnant women buying these bottles.

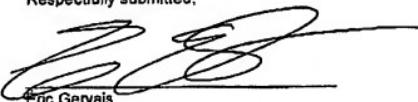
11. A Diclectin® with a graphical indicia of a pregnant woman applied on each tablet was launched in the Canadian market around the end of November 2002. The application of the indicia constituted the only change to the medicament. Absolutely no specific marketing was associated with this change.
12. Very surprisingly, we, at Duchesnay, observed that the sales of unit bottles of Diclectin® in 2003 for Canada increased by 14.8% with regard to those of 2002, which constituted an exceptionally high increase, as compared to the increases observed over the preceding years.
13. That increase was the average of significant individual increases in all territories of Canada (British Columbia, Alberta, Saskatchewan+Manitoba, Ontario, Quebec, Atlantic provinces), whether or not medical representatives were circulating therethrough.
14. For example, there were at that time four medical representatives in Ontario, where the sales increase observed between 2002 and 2003 was of 17.73%, and there was absolutely no medical representative in Saskatchewan+Manitoba, where the sales increase observed between 2002 and 2003 was of 17.8%.
15. By contrast, no increase in the natality rate was observed in Canada in 2002-2003, to which the increased number of sales could have been attributed.
16. Thus, in my opinion, nothing else than the application of a graphical representation of a pregnant woman on each tablet of Diclectin® has caused this surprising increase in sales.
17. Since Diclectin® is prescribed by physician, the increase in sales is most probably due to greater amounts of prescription refills.

VI. CONCLUSION**18. In my opinion:**

- 18.1 The exceptional increase of sales of Dilcetin® unit bottles observed in 2003 constituted an unexpected commercial success for the medicament.
 - 18.2 The commercial success of Dilcetin® observed in 2003 is solely due to the application of pregnancy-friendly Indicia on each Dilcetin® tablet at the end of 2002.
19. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Respectfully submitted,

11/oct/2006
Date



Eric Gervais